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Mini Review

Strategy for Developing a Smoking Cessation Program in Macedonia

Marija Zdraveska[1], Deska Dimitrievska[1]*, Mome Spasovski[1], Arben Rexhepi[1], Zoran Arsovski[1], Linda Kaljee[2], Alexander Plum[2], Amanda Holm[3], Magdalena Pop Trajkova Lazarevska[4], Monika Tushevska[1], Branka Pavloska[1], Nikola Chamurovski[1], Ana Naceva Rafajlovska[4], Irena Horvat[4], Bojana Badzakova[4] and Michael Simoff[5]

[1]Medical Faculty, Skopje, Macedonia

[2]Henry Ford Global Health Initiative, Detroit, Michigan, USA

[3]Center for Health Promotion and Disease Prevention, Henry Ford Health System, USA

[4]University Sts Cyril and Methodius, Skopje, Macedonia

[5]Department of Pulmonology and Critical Care Medicine, Henry Ford Health System, USA

***Corresponding Author:** Deska Dimitrievska, Medical Faculty, Skopje, Macedonia.

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Abstract

Macedonia has one of the highest smoking rates in Europe and ranks among the top ten globally. Although there is a moderately strict anti-smoking legislation, tobacco free policies are not financially supported and smoking cessation activities are not included in the regular educational process of health workers in the country. Smoking cessation is not considered a medical intervention, there is no consistent access to nicotine replacement therapy or other cessation medications, nor are they covered by health insurance.

The goal of the partners from Henry Ford Health System and the University St Cyril and Method in Skopje was to develop and adapt a Certified Tobacco Treatment Specialists program (aCTTS). A team of physician champions was created to facilitate implementing the program and to educate respiratory and internal medicine specialists, as well as general practitioners who proceeded treating patients for tobacco dependence. During the first four months of the intervention 64,668 patients visits were registered, 25,710 (40%) of them for tobacco-related diseases. Of the latter, 18,558 (72%) included smoking cessation counseling, which by itself is a great progress to reaching a striving population of smokers.

Keywords: *Smoking Cessation; Macedonia; Educational Strategy*

Tobacco kills almost half of its users. The World Health Organization (WHO) estimates that more than 7 million deaths worldwide are due to tobacco use every year, of which 6 million are active smokers, while more than 600,000 are non-smokers and exposed to passive smoking [1].

Smoking cigarettes is the most harmful risk factor, which is the leading cause of the global burden of disease, primarily in men and in the morbidity and mortality of chronic non-infectious diseases [2].

Macedonia is a country with 2,107,294 inhabitants, almost one quarter, approximately 500,000 live in the capitol, Skopje. Tobacco has been consumed in the region of Macedonia ages ago. Over the years, the characteristics and the profile of the smokers have changed, but the smoking rate remains on a very high level.

Smoking is not just a bad habit in Macedonia. Tradition of raising, processing and consuming tobacco is also involved, as well as social and cultural aspects Many Macedonian families earn their living from cultivation and processing tobacco. In some of the regions of the country, growing tobacco is the only source of income of the population. According to official data, the activities associated to tobacco processing contribute with 2.8% of the country's GDP. In the past there were numerous tobacco factories which worked with full capacity. During the past decade part of them have been closed or repurposed, but on the other side. Big tobacco magnates have entered the country with their business, upholding (preserving) the tobacco industry as a powerful enemy, managing to keep the high rate of smokers in Macedonia.

According to official data from 2013, 46.6% of the male and 26.8% of the female population in Macedonia are active smokers [3]. These numbers ascertain Macedonia to the top places in Europe by smoking rates. Consequently, Macedonia is on the second place, after Hungary, with incidence of lung cancer in males of 102 cases per 100,000 [4]. Up to two decades ago, smoking was allowed everywhere in the country, actually, there was no smoking ban whatsoever.

The data from a study conducted by the Institute for occupational medicine show that 35% of the workers smoke at their working places and 25.9 to 32.8% are exposed to passive smoking at their working environment. According to the aforementioned study, only 8% of the employees had actually quit smoking [5].

Macedonian businesses generally follow EU regulations banning smoking inside public places, but the rules are regularly broken in many restaurants, bars and hotels [6]. Smoking in the Republic of Macedonia is "socially accepted", unlike alcohol or psychoactive substances. This also is a unique example of the implementation of a dual policy, having in place a restrictive smoking ban in accordance with EU regulations along with high agricultural subsidies aimed at stimulating tobacco production [7].

Macedonia has a long tradition in the production and use of tobacco and tobacco products. Tobacco production account for about 78% of industrial crop production and one quarter of agricultural exports, a tradition that is deeply rooted in the social and economic culture of the country [8]. Smoking cigarettes is a widespread and serious public health problem which seriously affects the health of the population in Macedonia [9].

The prevalence of tobacco use is higher than the average of the European countries and in 2017, 46% of the adult population (15 - 64 years old) were active smokers, while 55.4% used tobacco during their lives (cigarettes, cigars or pipes). The highest percentage belongs to the age group 35 - 44 and in terms of sex distribution, 54.1% of active smokers are male, compared to 33.3% of females [10].

If we compare these data with the study on the assessment of the prevalence of smoking in 187 countries in the 1980 to 2012 period, when the prevalence was 35% and 36.7% in 2012, there is an upward trend and Macedonia is ranked in the top 10 countries with the highest numbers of smokers.

In addition, Macedonia is in the group of countries along with France, Austria, Andorra, Hungary and Chile, where the prevalence of cigarette smoking among female smokers is higher than 25% [11].

According to the ESPAD study conducted in 2015 in the Republic of Macedonia, about 24% of students smoked cigarettes in the last 30 days, a percentage higher than the average of the participating countries in the study [12]. However, the Republic of Macedonia is among the countries with low prevalence, regarding early smoking (before 13 years of age) and the practice of risky behaviour among primary and secondary school students [13].

In the period between 2005 and 2010, the Government of the Republic of Macedonia launched a campaign against smoking, which included legislation to ban smoking in public places and educational programs for tobacco harmfulness in schools. However, five years

after the campaign, there is no significant reduction in the prevalence of active smokers among workers, 35.4%, compared to 36.8% in 2005. High prevalence of smoking workers who work in the office remains, or 30.2% despite the ban on smoking at the workplace [14].

The prevalence of smoking among doctors is also very high in Macedonia; 29% in 2014. However, compared to 1999, when 42% of doctors used tobacco, there is a downward trend or 30% for a period of 14 years [15]. Nevertheless, 35% of doctors who smoke, rarely do advise their patients to stop smoking, 62% did not know about the pharmacotherapeutic modalities used for quitting smoking and the population of doctors who smoke has more liberal attitudes towards the ban on smoking in public places. One of the more important information in this research is the interest shown by doctors, over 60%, regarding the need for training for quitting smoking.

According to a survey on the social determinants of smokers in Macedonia, there is a positive association between the smoking status and place of residence, in rural areas; gender, predominantly male; ethnic, primarily Albanian, Macedonian or Roma and half of the smokers were unemployed. Factors that along with the perception that smoking is a "socially acceptable" habit should be taken into account when implementing policies and legislation [16].

As a country we do not have a regular access to nicotine replacement therapy and anti-addiction drugs so starting of a Center or Program for smoking cessation was a "mission impossible". Nicorette gum as a replacement therapy was present on our market in the dosage of 2 and 4 micrograms up to eight years ago, but it was retracted from the pharmacies due to "low or no interest". Cytisine (Tabex) was available until five years ago. None of the other prescribing medication which are worldwide accessible for smoking cessation were ever in use in our country. In our pharmacies only herbal mix plus nicotine is present as patches for trans-dermal application. These patches contain *Ginseng, Garcinia, Passiflora*, Mint and non-declared amount of nicotine, so they cannot be used as a validated replacement therapy.

On the other hand, physicians in our country have lack of time to deal with concealing due to a big number of patients for check-up. Smoking cessation is not yet validated as a medical intervention and is not covered by health insurance. Furthermore, the low socio-economic status of the population is related to poor health education about the risks of smoking and consecutively only small part of smokers are willing to quit.

Contribution to the high smoking prevalence in Macedonia are the legal regulations. Until 1995 there was no smoking ban. The first law restricting smoking in the Republic of Macedonia was adopted in 1995. This law regulates the protection against the harmful effects of tobacco smoking and other tobacco products, the preservation of a healthy environment. It brought a ban on smoking in certain public spaces and a ban on advertising cigarettes. This law prohibits smoking in: Facilities in which educational activities are performed and facilities for nursing and accommodation of children and students; health care and social institutions; Closed and open rooms in which sporting events, cultural manifestations, gatherings and other public events are held; means for public transport of passengers; Facilities in which food is produced, prepared, served, sold or consumed; Premises where meetings are held and other premises (halls, offices, waiting rooms and corridors). It restricts advertising cigarettes and trademarks of cigarettes and tobacco industry in public media. It was forbidden to sell cigars and tobacco to persons younger than 16 years. The cigarette manufacturer is obliged to print a message on the front of the package with warning information that smoking is harmful to health.

In 2008 and 2010, a new low for regulation of smoking was issued, with some additional amendments. With this law, it is forbidden to advertise the tobacco products and tobacco industry in any form and place. Smoking is forbidden in all indoor and outdoor areas where sport events are held. Smoking is forbidden in all closed premises where cultural, entertainment events, gatherings and other public events are held. Smoking is forbidden in areas outside the business premises, intended, arranged and equipped to provide catering services that contain accessories (roofs, walls, glass, foil, plastic or nylon sections and similar) with which the space is closed on all sides and thus becomes a closed space. Smoking is permitted exclusively outside the business premises (terrace, summer garden and similar) only if the area is covered and is open at least on three sides without a partition (glass, foil, plastic or nylon sections etc.) or open space that is not covered with tendons, umbrellas (and similar), which is laterally closed (outdoor discos, terraces, summer gardens, etc).

Unfortunately, in October 2017, the Parliament of the Republic of Macedonia, passed an amendment, allowing smoking in outdoor spaces of the restaurants and pubs, even if they were closed with barriers from all sides. This liberalization of the law for tobacco consumption put Macedonia two steps back in the struggle for smoking and tobacco prevention.

Development of a certified, comprehensive, culturally appropriate smoking cessation training program for healthcare providers in Macedonia

Determination of partnership

The goals of the partner organizations, the Saints Cyril and Methodius University of Skopje, Macedonia and Henry Ford Health System (HFHS) were represented in our commitment to improving care for tobacco consumers in general, thereby transforming lives and communities through health and wellness, one person at a time.

Background of educational programs

According to Siegel [17], nearly one billion dollars were spent in 2001 in the USA on state-wide tobacco control programs, resulting in significant reduction of smoking prevalence, cigarette consumption as well as improvement of positive tobacco-free behaviour, such as reduction of indoor smoking and promotion of smoking cessation. Various tobacco cessation programs are available and recommended in the numerous existing publications. Telephone based programs with repeated brief counselling are interesting because of their low cost and wide accessibility, especially when addressing broad populations, for example in lung cancer screening [18-20]. Web based smoking cessation support programs, combined with nicotine patch replacement therapy are described providing efficacy of 23.1% to as high as 39.1% adjusted six-month cessation rate, depending on the depth of intervention and the baseline characteristics of the subjects [21,22]. On the other hand, one to one, individualized, counselling programs, providing up to 6 months support and counselling with certified tobacco specialists, such as the ones practiced in the Mayo Clinic or Henry Ford Health System, have proven their efficiency throughout the years of practicing experience (32% quit rate for 2017), we decided to adapt and implement this type of smoking cessation program in Macedonia.

Estimating the need for a certified educational program in Macedonia

To date, there is very limited data on the barriers and facilitators for implementation of a health-system based smoking cessation program in Macedonia or the region. There are no organized and structured educational programs for smoking cessation available, nor is this subject addressed within the formal education of health professionals. One attempt to disseminate and implement a support program for smokers who would volunteer for tobacco counselling was registered 5 years ago, organized by the Institute for public health and the Institute for lung diseases and tuberculosis in Skopje, but with very limited resources and success. In a setting of extremely high prevalence of smoking (about 37%, 46.5% for men and 26.7% for women) and week support from the institutional and health services, the health workers in Macedonia are striving for support in their efforts to fight the tobacco problem [23,24].

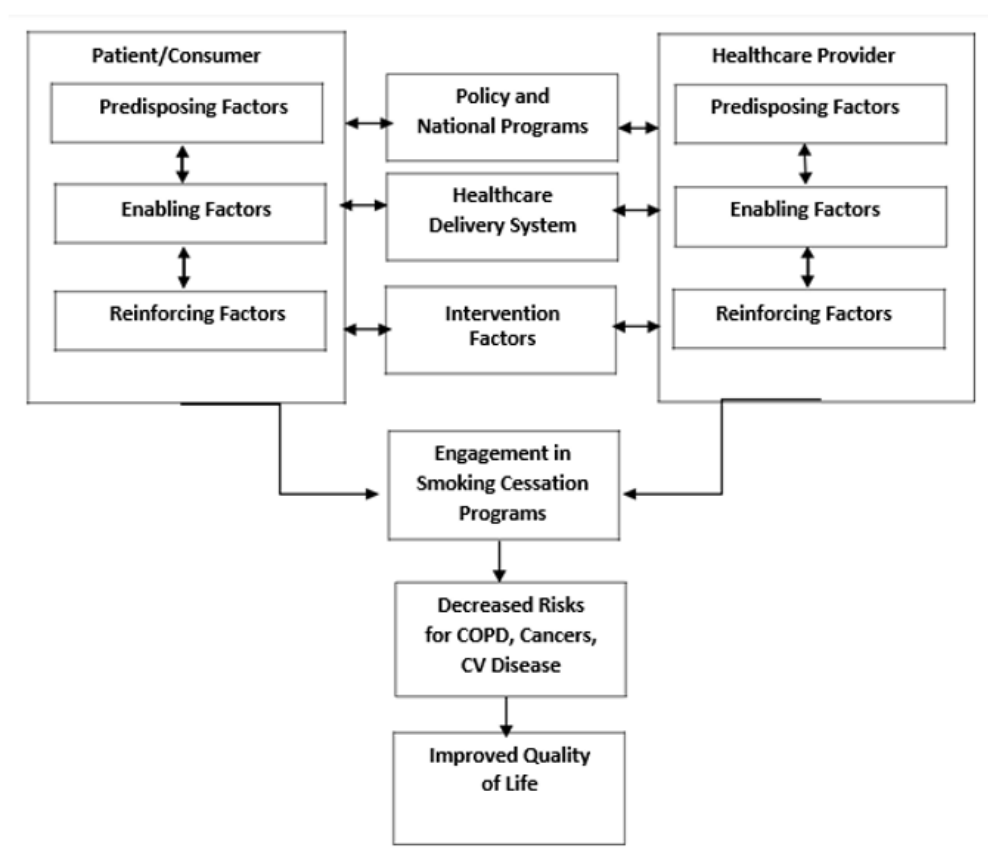
Allocating project goals and partners

In order to create and implement a program for education of health workers for tobacco cessation in Macedonia, we decided to join in mutual effort the expertise, of the certified tobacco specialists from the "Freedom of smoking program", the experience in treating smoking related diseases and the extensive knowledge and experience in disease prevention and treatment, and in coordinating training initiatives and field procedures, from the Henry Ford Health System team of experts, with the highly motivated group of specialists in respiratory medicine and public health from the Medical faculty at the Sts Cyril and Method University in Skopje. Important financial support was provided by the Global Bridges at Mayo Clinic and Pfizer Research Grants for Learning and Change, obtained in May 2016.

Determination of project methodology

Theoretical framework

In order to identify core concepts and procedures in the adaptation and implementation of the Certified Tobacco Treatment Specialist training and to identify effective future interventions strategies, we have based our research on a modified 'systems model of preventive clinical care' [25]. A unique feature of this model is the inclusion of factors related to the broader policy landscape, the health system, the health care provider and the patient within a single framework. The categories were defined and details regarding application of this framework for the current study are outlined in below in figure 1.



Stepwise structure of the project

Phase 1: Formative research

For the purpose of estimating typical features and problems related to tobacco in Macedonia, it was necessary to obtain information regarding the socio-cultural and psychological factors which affect tobacco use and smoking cessation efforts from the perspectives of mul-

tiple stakeholders. Formative research includes assessment of tobacco and smoking cessation policies and programs, and socio-cultural and psychological barriers and facilitators for successful implementation of a smoking cessation program within a medical setting. It was also used to identify populations which may be at higher risk for tobacco use and potential avenues for targeted intervention messaging for those populations [26].

In order to determine the local attitude towards smoking, tobacco consumption habits and community features and needs, a windshield survey was conducted in 6 regions in Macedonia, with diverse characteristics.

As part of the formative research process, specifically structured and community based qualitative interviews were prepared and conducted with key policy stake-holders (key informant interviews), health care providers and pulmonary patients.

Crucial part of the formative research was to explore existing initiatives of the healthcare providers to advise their patients to quit tobacco and leverage relationships to develop a technical approach with a high likelihood of success. Data were translated, elaborated and incorporated in the process of adaptation of the certified tobacco cessation program.

Phase 2: Adaptation of a certified tobacco treatment specialist training program

Analysis of the data obtained in the formative research provided a basis for identifying of the core elements of the training program. Core elements are those components of the intervention thought to be critical aspects of the original effective program without which it is unlikely that the program would remain effective. The "Diffusion of Effective Behavioural Interventions-DEBI" paradigm advises that in implementing the effective program, if changes are made from the original, the new implementation protocol should retain all of the identified Core Elements [27]. Defining vital versus adaptable core elements is crucial for adaptation, translation and successful acceptance and implementation of public health intervention programs. In this process it is necessary to take into consideration the social and cultural diversities of the society from which the program in stake originates, and the targeted population. In the process of adaptation it is necessary to determine "limits of allowed change" of the core elements in order to ensure successful acceptance, but in the same time to preserve the elements which determine the essential and important characteristics of the program itself. Preparation of related materials [28,29] for the Certified Tobacco Treatment Specialist training followed thorough analysis of the core elements.

Phase 3: Allocation and education of physician champions

Five physician champions from the Medical faculty in Skopje, Macedonia (four pulmonary specialists and one public health professional) were selected to be the core partners for the adaptation, conducting and implementation of the Certified Tobacco Cessation Educational Program. A "train the trainers" educational course was conducted in March 2017, at the HFHS, Detroit Michigan, USA. Adaptation of the training program, aimed to educate healthcare providers on the need, rationale and techniques for counselling patients to quit tobacco, was incorporated in the program of the course, resulting with preparation of 15 Training Modules, encompassing all essential components of the tobacco treatment program.

Phase 4: Transfer of knowledge

The educational course for training physicians in Macedonia was realized in May 2017 at the Medical Faculty in Skopje. Pulmonary physicians, internal medicine and public health specialists, as well as family doctors presented the 98 participants who volunteered to take part in the 2 day-educational program for Tobacco cessation. The specially adapted learning modules were presented by the USA expert team and the Macedonian physician champions. Hand on workshops were organized for small groups in order to simulate the tobacco counselling process. Pre and post educational evaluation of knowledge was performed and plans for further implementation of the certified tobacco cessation program within the population of patients of each participating physician were defined.

Phase 5: Implementation of the tobacco cessation intervention

Each trained physician was instructed to detect smokers within the population of his patients, their characteristics, heaviness of smoking index and willingness to quit smoking. Structured smoking cessation advice and support was offered to all motivated patients. Unfortunately, no pharmacological support (nicotine replacement preparations, nicotine receptor agonists nor specific antidepressants) are available in Macedonia, so counselling was limited to informative and motivational interviewing. Weakly logs for registering the doctors' activities are collected by trained research assistants and included in the evaluation process.

Phase 6: Estimating the effect of the intervention - pilot patient survey

A short, specially structured questionnaire for patients, was created and distributed to collect data from a pilot group of patient-smokers, who underwent the process of tobacco cessation counselling. The purpose of this questionnaire is to estimate the effect of the intervention, as well as the true readiness and motivation of the patients to definitely quit smoking.

Process evaluation

Evaluation tools were prepared for each phase of the program, and data were prepared for analysis. Outcome evaluation is ongoing and the presentation of results will show the degree of effectiveness of the intervention.

Conclusion and Plans for the Future

The analysis of the results from this study is in progress and shall be conducted by the Department for Statistical Analysis at the Henry Ford Health System. The data are to be presented in a dedicated paper, hopefully answering the dilemma whether our intervention was successful and efficient.

If proven adequate and productive, we plan to seek for wider implementation of the adapted certified educational program for tobacco cessation locally, to other categories of health professionals in Macedonia and regionally. Steps are already taken to offer the intervention to the surrounding Balkan countries, where the prevalence of smoking is comparably high as in Macedonia and tobacco cessation programs are on an equally low level.

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