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THE POLICIES AND PRACTICIES FOR PRIMARY PREVENTION AND EARLY DETECTION OF CERVICAL CANCER IN MACEDONIA

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FOREWORD

Cervical cancer is one of the most important public health issues worldwide. The effects of its early prevention and appropriate treatment influences the overall woman's health and life, but also the wellbeing of her children, family and the community in general.

More than 250.000 women die from cervical cancer annually. In Macedonia approximately 200 women are diagnosed with cervical cancer, and almost half of them die as a result of this disease. HERA believes that the majority of deaths could be prevented if appropriate access to sexual health services, sexual education and information exists. Additionaly, HERA stands for quality organized screening programs, which are of key importance for the decrease of the prevalence of the cervical cancer and for promotion of the sexual and reproductive health and rights of the women in general.

This is why HERA supported the master thesis work of Ms. Irina Luceska, who analyses the current situation and challenges for improvement of the national mechanisms for cervical cancer prevention, with a comprehensive scientific approach. We sincerely believe that the analysis and the conclusions of this research will encourage our policy makers to improve the current national mechanisms, especially the quality and scientific approach in the organized screening and the participation of the civil society.

Bojan Jovanovski – H.E.R.A.

LIST of ABBREVIATIONS

ACCP	- Alliance for Cervical Cancer Prevention
ACS	- American Cancer Society
ASA	- American Sociological Association
GDP	- Gross domestic product
CIN	- Cervical Intraepithelial Neoplasia
ECDC	- European Center for Disease Control
ENCR	- European Network of Cancer Registries
EEA	- European Economic Area
EU	- European Union
HIF	- Health Insurance Fund of Macedonia
HPV	- Human Papilloma Virus
IARC	- International Agency on Research on Cancer
KAP	- Knowledge, Attitudes and Practices
NGO	- Non-governmental Organization
PAP	- Papanicolau (test)
PHC	- Primary Health Care
QALY	- Quality Adjusted Life Year
PPS	- Purchasing Power Standard
SIHP	- State Institute for Health Protection
STI	- Sexually Transmitted Infection
WHO	- World Health Organization
WHA	- World Health Assembly

EXECUTIVE SUMMARY

Cervical cancer is the second largest cause of female cancer mortality worldwide, "with an estimated 493.000 new cases and 274.000 deaths in 2002" (Parkin et al. 2005, p.91) and projections of further increase in future (WHO 2005). The disease generally affects women at younger age than other cancers do (WHO 2005), with the majority of cases appearing between ages 35 and 50, when many women are actively involved in their careers or caring for their families (Gustafsson et al. 1997). The persistent infection with high-risk (oncogenic) human papillomavirus (HPV) genotypes is identified as the necessary prerequisite for development of cervical cancer and its precursors (Bosch et al. 2002; Muñoz et al 2003).

The main element of the early detection of cervical cancer is the screening program, which according to the international recommendations should be organized, population-based, with effective quality assurance throughout the screening process, in order the public health benefits and cost efficiency to be achieved (The Council of EU 2003; WHO 2006; European Communities 2008a). Since 2006 the main focus of the primary prevention of cervical cancer is the HPV vaccine, after a long period when the emphasis was placed on the control of co-factors (WHO 2002). The available studies reveal excellent efficacy of the vaccine and good safety profile (Harper et al. 2006, ECDC 2008; WHO 2007). However, its high price is a big challenge the health community is faced with. As the vaccine is effective against only a portion of the causative agent, the need of integration of the prevention strategies – the vaccination with the screening, and the strategies for education, awareness rising and behaviour change for prevention of the infection and risk factors is evident (Pollack et al. 2007).

Cervical cancer is one of the most frequent types of cancers among women in Macedonia, with crude incidence rate of 20-28/100.000 and mortality rate of 5-7/100.000 (SIHP 2006). The highest incidence rate is between 45 and 54 years of age (IARC 2002). The screening coverage in the country is only 10% of the target female population annually, despite the fact that it was traditionally offered free of charge or with a low level of co-payment (Gynecology clinic public presentation 2007).

Having recognized that the incidence of cervical cancer, which is among the highest in Europe, and the low cervical cancer early detection coverage, justify investment in programs that will deal with this health problem, the Government of Macedonia decided to act in three levels: strengthening the existing, integrated early detection activities; designing and implementing vertical "campaign–like" program for cervical cancer screening and promotion of the possibility for primary prevention, through making the HPV vaccine available to the citizens.

The research explores how the current national policies and programs related to cervical cancer primary prevention and early detection in Macedonia are being designed and implemented to provide meaningful public health benefit

(reduction of incidence and mortality). A comparative analysis of the national cervical cancer prevention policy with the processes and programs related thereof was performed, by characterizing the basic organisational context of the programs and through the frame of reference of the international guidelines and recommendations.

This study followed a predominantly qualitative methodological approach, in a form of formative evaluation of the design and implementation of the programs, followed by a comparative analysis. It was performed in the towns of Skopje, Prilep and Kumanovo. The data collection techniques used were in-depth interviews with different stakeholders pertinent to the field, research of public official documents and media accounts, and non-participatory observations of the public gatherings (workshops, meetings), which took place as a part of the national cervical cancer prevention campaign.

The research revealed that the policies and programs for cervical cancer prevention, as designed and implemented, show the determination of the Government for the rights-based approach towards the promotion of the "women's health", following the principles of affordability and non discrimination on the basis of health-insurance status, by offering possibility for all women to perform free-of-charge PAP examination, and by considering the inclusion of the HPV vaccination in the national immunization schedule, thus making it available as a free-of-charge vaccine for all girls aged 12. However, certain important elements of the policies and practices are shown not to be formulated and implemented following the best-practice and the existing evidence in the field, and should be carefully reconsidered having in mind that two complex and demanding population-based programs – organized screening and HPV vaccination, are being announced to commence in 2009.

Although the tendency for inclusion of the stakeholders, especially the civil sector, in the design and implementation of the programs and processes related to cervical cancer prevention in the country is evident and should be strongly supported, rethinking of the participatory approach, paying attention to the needs, opinions and attitudes of all stakeholders, both the professionals as well as the female population should be considered.

The scientific approach towards the decision making process should be enforced, by performing baseline economic and socio-cultural assessments, tailored to the local circumstances, focused on the technology itself (primarily the HPV vaccination) and the beneficiaries. Clear determination of the basic guiding elements and principles (the target population, target age range and frequency of screening), essential for an activity to be understood as taking place in a context of a program, and their communication with the stakeholders is shown to be a priority. While the promotion segment, through mass education of the general population is given great deal of attention, the process of personalized communication with the clients, the women and their families, in a form of counselling is being neglected.

The creation of a culture for quality assurance in health in general is an imminent need, which would have its role in the cervical cancer prevention activities as well. Some of the measures which could be considered are: creating a sound legislative background, proper assessment of the available resources, improving the current health information system towards a more comprehensive and reliable model, applying qualitative performance measures alongside quantitative, promoting the participatory approach towards the evaluations design.

The findings and recommendations given as a result of this research, are expected to contribute to dimensioning, focusing and rationalising the envisaged activities and resources, identification and understanding of the obstacles, as well as the hidden opportunities, useful for improving the current and design of future programs.

BACKGROUND

Burden of disease

Cervical cancer is the second largest cause of female cancer mortality worldwide, "with estimated 493.000 new cases and 274.000 deaths in 2002" (Parkin et al. 2005, p.91) and projections of further increase in future (WHO 2005). The disease generally affects women at younger age than other cancers do (WHO 2005), with the majority of cases appearing between ages 35 and 50, when many women are actively involved in their careers or caring for their families (Gustafsson et al. 1997). Although the burden of the disease is much higher in the developing countries, its significance can not be underestimated in the developed world as well. In the EU approximately 34.300 women were diagnosed and 16.300 died from the disease in 2004 (Arbyn, Autier and Ferlay 2007). The persistent infection with high-risk (oncogenic) human papillomavirus (HPV) genotypes is identified as the necessary prerequisite for development of cervical cancer and its precursors (Bosch et al. 2002; Muñoz et al 2003). Fifteen out of 40 HPV types which infect the genital tract are found to be oncogenic, namely the types 16, 18, 45, 31, 33, 52, 58, 35, 59, 56, 39, 51, 73, 68 and 66, in descending order of frequency identified in the cervical cancer specimens in an international survey conducted by Muñoz et al. (2004). "HPV is the most common STI worldwide, affecting an estimated 50-80% of sexually active women at least once in their lifetime" (ACCP 2004, p.5). Most HPV infections, however, are transient or self limited, and the majority of those who develop preinvasive disease, or dysplasia, have spontaneous regression and resolution of the dysplasia, resulting either in no symptoms or producing low-grade intraepithelial lesions (American Cancer Society 2002). In the minority of women where HPV infection progresses into cervical cancer, the average duration for a pre-cancerous lesion to develop into invasive cancer if left untreated is 10-12 years (European Communities 2008a).

There is significant difference in the incidence and mortality rates among the EU countries, ranging from world-standardized mortality rate of 1,1/100.000 in Finland, to 13,7/100.000 in Romania (Arbyn et al. 2007; Arbyn, Autier and Ferlay 2007). Time-trend studies in some European countries indicate that the decrease in cervical cancer incidence and mortality rates has been attributed to the organized approach towards the screening program (IARC 2005).

According to the IARC Globocan database, as well as the national epidemiologic data of the State Institute for Health Protection - SIHP, cervical cancer is one of the most frequent types of cancers among women in Macedonia. However, the figures produced by these institutions vary, as presented in Table 1. The highest incidence rate is between 45 and 54 years of age (IARC 2002).

Table 1: Cervical cancer incidence and mortality data - Macedonia

	IARC – Globocan database (IARC 2002)		State Institute for Health Protection (SIHP 2006)	
	age-adjusted rate	crude rate	crude rate	numbers
Incidence	13,9/100.000	16,4/100.000	20-28/100.000	~200-280
	2002 - estimates		*1995-2005 data*	
Mortality	7,6/100.000	9,7/100.000	5-7/100.000	~10-14
	2002 - estimates		*2000-2005 data*	

The international perspective

Bringing the "Resolution on Cancer Prevention and Control" in 2005, the World Health Assembly acknowledged the increased importance of the public health implications and the rising trends of cancer risk factors and cancer incidence and mortality worldwide. While in the past it was considered that the problem of the chronic diseases belonged mainly to the developed world, the situation now shows a completely different picture, as the burden of chronic diseases in the 21st century has already became a worldwide issue, with 80% of the deaths occurring in low and middle income countries (WHO 2005a). The cancer control is set as a comprehensive set of actions, starting from primary prevention of the disease and control of the risk factors; through early detection strategies, as are the screening and physical examination; diagnosis and treatment; to palliative care for advanced disease (World Health Assembly 2005).

Already in 1968 the WHO set the principles of screening for disease as a feasible method for their secondary prevention (WHO 1968). If the cost of screening, "the tendency in the medical profession to wait for patients, rather than to look for the disease in the population and the inadequate knowledge of the principles and practice of screening" were the three factors mentioned as possible obstacles to the widespread implementation of screening for a disease (WHO 1968, pp.7-8), it is expected that now, after four decades of intense development in the medical and health science and practice, these would be overcome. However, as the importance of screening for early diseases detection as one of the disease control methods, is restated in the 1990ies by the institutions like the WHO and the Council of Europe, shows that there is still much to be done in this area (WHO 1999, Council of Europe 1994). In the time being the efficacy of screening is proven for only a few cancer types, such as the breast cancer, the cervical and the colorectal cancer, which is reflected in the 2003

recommendations of the Council of the European Communities (The Council of EU 2003, p.35).

In the summarised framework given by the World Health Assembly in its Resolution on Cancer Prevention and Control, it is recognised that: "among all cancer sites, cervical cancer, causing 11% of all cancer deaths in women in developing countries, has one of the greatest potential for early detection and cure; cost-effective interventions for early detection are available and not yet widely used, and the control of cervical cancer will contribute to the attainment of international development goals and targets related to reproductive health" (World Health Assembly 2005, p.1).

The control of cervical cancer, as a chronic disease which affects the female reproductive organs, with etiology of a sexually transmitted infection, needs special attention. The disease has a unique pattern that it affects the woman in its early reproductive age, as well as the later stages in life, a fact that has special ethical and other implications, important at all levels of comprehensive control, from primary prevention to treatment. The availability of methods for immunization, screening, diagnosis and triage is increasing (IARC 2005). This fact, combined with the high prevalence of HPV infection could put substantial financial and human resources burden, even in the well-off countries, in case prevention programs are not carefully planned.

The first WHO global strategy on reproductive health adopted in 2004 (WHO 2004), addresses the problem of cervical cancer as a sexually transmitted infection of the reproductive tract. The WHO "Regional Strategy on Sexual and Reproductive Health", which treats this issue from a closer regional perspective, clearly states that the "mortality related to cervical cancer has increased in many countries of the central and eastern Europe, mainly due to the lack of population based screening program" (WHO 2001, p.5). One of the defined objectives of this strategy is to reduce the incidence of cervical cancer, through implementation of screening programs for early detection of cervical pre-cancer and for management of invasive cervical cancer (WHO 2001, p.13).

Being defined by the WHO (2006) as the core element of the early detection component of cervical cancer control, it is necessary to stress that the screening program is characterized by two main features in almost all international strategies and guidelines. According to the scientific evidence, reflected in the recommendations provided by the Council of EU (2003), the WHO (1999, 2006), European Communities (2008a), the screening should be organized and population-based, with effective quality assurance throughout the screening process, in order the public health benefits and cost efficiency to be achieved:

> The public health benefits and cost efficiency of a screening program are achieved if the program is implemented systematically, covering the whole target population and following best-practice guidelines….Systematic implementation requires an organisation with a call/recall system and with quality assurance at all levels, and an

> effective and appropriate diagnostic, treatment and after-care service following evidence-based guidelines. (The Council of EU 2003, L327/35).

Speaking about the primary prevention of cancer in general, the emphasis in the past was placed on the control of the co-factors (WHO 2002). However, even at the dawn of the HPV vaccine invention, there was a noticeable support from the international community towards its development (WHA 2005) most probably driven by the fact that the Hepatitis B vaccine has for long been the only available vaccine against cancer related disease. The launch of the HPV vaccine on the markets in 2006, meant a new era in the cervical cancer prevention strategies. The vaccine efficacy, proven for a minimum period of 4-5 years is nearly 100 % in preventing persistent infection by the vaccine genotypes HPV 16 and 18 (Harper et al. 2006). This vaccine shows good safety profile and only mild side effects (ECDC 2008; WHO 2007). In the same time when this invention is recognised as a "millennial" development, winning much public attention, the health community is faced with many challenges. The vaccine is effective against only a portion of the causative agent, thus the need of integration of the prevention strategies – the vaccination with the screening, and the strategies for education, awareness rising and behaviour change for prevention of the infection and risk factors is evident. The grey zone of duration of protection, the cross protection, the vaccine compatibility, and data on children and infants are some of the knowledge gaps which affect its introduction (ECDC 2008). The special ethical concerns of vaccinating young girls against a sexually transmitted infection, vaccination of boys and men, the delivery strategies, and of course the financial perspective are some of the critical programmatic issues (Pollack et al. 2007).

Terminology

The definition of screening given by the UK National Screening Committee is that "**Screening** is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications." (2009). The **cancer screening** is defined by the Commission of the European Communities in its First Report on the Implementation on the Council recommendations on cancer screening as "prophylactic examination of apparently healthy individuals for the purpose of early detection and treatment of cancer" (European Communities 2008b). Holland on the other hand in his paper "Screening for disease – considerations for policy" stressed that "it is important to distinguish between **population screening**, where people thought to be at risk are invited for screening, as in the national programs for cancer of the breast and cervix, and **opportunistic screening**, for prevention or case-finding

where individuals have sought medical advice for a specific symptom or complaint and opportunity is taken to suggest various other tests, such as the measurement of blood pressure or cholesterol" (2006, p.1). The "population screening" is also referred to as **organised or invitational screening** (Anttila et al. 2004) and it requires high degree of organisation in order to assure that the invitational activities are performed reliably and effectively and are adequately coordinated with the subsequent steps in the screening process (European Communities 2008b).

The assessment of the quality assurance strategy as one of the core elements of a successful program, in the context of this research will be limited to exploring the **process and performance** measures, i.e. the assessment of the **"evaluability"** of the programs and processes.

> **'Evaluability assessment'** is an assessment prior to commencing an evaluation to establish whether a programme or policy can be evaluated and what might be the barriers to its effective and useful evaluation. It requires a review of the coherence and logic of a programme, clarification of data availability, an assessment of the extent to which managers or stakeholders are likely to use evaluation findings given their interests and the timing of any evaluation vis a vis future programme or policy decisions. In addition to assisting evaluators, 'evaluability assessment' has been acknowledged as useful for policy makers, programme managers and other stakeholders or partners (European Communities 1995-2008).

As the processes and programs related to cervical cancer prevention in Macedonia are expected to be ongoing, basic evaluability assessment is seen as an appropriate and useful technique, as it "can be used to determine the needs of information not only for the future evaluation of the programme, but also for monitoring its implementation and to follow-up the delivery system of the activities planned" (European Communities 1995-2008).

Macedonia - the context

Macedonia is a relatively small European country, situated on the Balkan peninsula. It was one of the federal states of the Socialist Federative Republic of Yugoslavia. With the fall of Yugoslavia in 1991 Republic of Macedonia gained independence. As a transitional country it is in the process of transformation of the systems towards the European model, as a result of the tendency for joining the EU. The transition of the systems of the society from centrally planned towards market-driven and the decentralization are the main elements of the reforms. "All reform initiatives in the health care are undertaken with the aim of sustaining access for the whole population to a comprehensive health system, as well as improving the quality of health services and enhancing financial sustainability" (Gjorgjev et al. 2006).

Macedonia covers an area of 25.713 km2 and population of 2.045.177 (2007 estimates). The country's population lives mostly in the urban areas ~58%, with ~25% living in the capital Skopje. The birthrate in the period 1997-2007 is ~2,1%; however aging of the population is evident, with the share of the population aged 0-14 decreased from 23,5% to 18,5% and the population over the age of 65 increased from 9,3% to 11,4% in the previous 10 years. The population 14-65 represents ~70% of the total. In average there are 107 newborn boys over 100 girls and ~11.300 newborn girls in the years 2001-2007 (State statistical office 2008a, pp.5-9).

The country is divided in 30 health regions: the Skopje health region covers a population of ~590.000, Prilep ~96.000, and Kumanovo region covers population of ~139.000 (SIHP 2005, p.12).

"Macedonia shares the disease prevalence pattern of that of other European countries: cardiovascular diseases, cancer, mental health problems, injuries, violence and respiratory diseases represent the most prominent causes of morbidity and mortality" (Gjorgjev et al. 2006). The cardiovascular diseases are the cause of death in 57,7% of the cases (State Statistical Office 2008a, p.12).

In table 2 the basic health care indicators for Macedonia are shown in relation to the EU countries. The infant mortality rate is an indicator which shows significant differences than the EU figures.

Table 2: Basic health care indicators- Macedonia / EU

	Macedonia	EU27
Life expectancy at birth m/f (2004)	71,5 / 75,8	75,2 / 81,5
Infant mortality per 1000 life births (2006)	11,5	4,7
Maternal mortality ratio per 1000 life births (2005)	10	13

Source: European Commission 2008; WHOSIS 2009

The estimated GDP of Macedonia for 2007 accounts to 7.400 PPS per capita (Eurostat 2008), which compared to the EU-25 average of 24.900 PPS, represents ~30%. The total public expenditure for health of the state in 2006 was 8,2 % of the GDP, which accounts to 350 million $ in total or ~180 $ per capita (WHOSIS 2009). 37 % (~130 million $ in total) were dedicated to drugs and other medical consumables.

The health care in Macedonia after the independence is financed through social health insurance, which is the main financing source of the health sector. This insurance scheme is designed to cover the great majority of the citizens of Macedonia and their families which are registered through the institutions of the system: the employed citizens, the unemployed, the farmers, the retired citizens, the citizens which are under social protection, the citizens engaged in the religious communities etc. (Official Gazette of Republic of Macedonia 2000). The Health Insurance Fund (HIF) is a single national purchaser of health services, and

as such it collects the compulsory contributions, allocates the funds, contracts and supervises the providers. The HIF's activities are closely supervised by the Ministries for Health and Finance. Significant level of 85% of the total health sector services are financed through the insurance schemes, while the rest are donations, Ministry of Health's programs and the out-of –pocket money of the citizens paid for the private services (HIF 2008a). The statutory health insurance enables access of the insured persons to the health care at primary, secondary and tertiary level, for preventive activities, diagnostic procedures, treatment and care (HIF 2007a). This basic benefits package, has its roots in the socialist times of the country. It is considered very comprehensive, but quite expensive when correlated with the health budget of the country. This in turn results in questionable quality of the services. One of the reforms processes which is currently undergoing, is the re-consideration of the basic benefits package. It is estimated that ~4,2% of the population is not covered by the health insurance schemes, and therefore is not entitled to the health care benefits (HIF 2007a).

The health care is delivered through a system of primary, secondary and tertiary health care facilities. While the primary and secondary facilities are spread all over the country, the tertiary health care was, until recently, centralized in the capital – Skopje. In 2005 and 2008 two more secondary hospitals in two other towns were transformed in tertiary level hospitals.

An important element of the health care sector reforms in Macedonia, which take place with accelerated intensity in the previous 3-4 years, is the privatization of the primary health care services – the general practitioners, dentistry, occupational medicine, children's health care, women's health care (gynecology) services and the pharmacies. The primary health care facilities which were previously in the public sector, were given for a concession to the health professionals who performed the services. The provider payment method used for the primary care services is capitation. The service contracts which the HIF has with the concessionaires are on an equal bases with the ones which the HIF has with the other private primary health services. The primary health care services, except for the pharmaceuticals, are free of charge for the users (Official Gazette of Republic of Macedonia 2001). The primary health care is organized in such a way that every insured inhabitant selects his/her primary physician. In order to use the secondary and tertiary level facilities, a referral from the selected primary physician is needed, who in this sense acts as a gatekeeper of the health care system.

Every citizen of Macedonia under its Constitution has a right to health care (Official Gazette of the Republic of Macedonia 1992). The Law on health protection defines a list of the guaranteed rights, needs and societal interests for every citizen of the country, regardless of whether their health insurance is regulated or not (Official Gazette of the Republic of Macedonia 1991). As these rights can not be guaranteed for the citizens without regulated health insurance

through the health insurance schemes managed by the HIF1, they are treated under special health programs of the Ministry of Health. The health prevention and the immunization programs are traditionally within their framework (Ministry of finance 2008). Specially formulated cervical cancer prevention program was included in 2005, but it is actively implemented since 2007.

The immunization is performed as a routine childhood immunization programme against number of diseases, as well as vaccination for other diseases under epidemiologic indication. Other vaccines, like the flu vaccine, meningococcus, pneumococcus etc. are available as voluntary vaccines. The decisions on which vaccines should be included in the scheme are brought by a Committee for Immunization and Commission for Communicable Diseases. The vaccination coverage in the country has been traditionally high, and in general is estimated to be 90-97% for DiTePer, Polyo, HepB, BCG in the previous 15 years (WHO 2009).

Cervical cancer prevention in Macedonia

The cervical cancer control in Macedonia was performed through a screening program, which was integrated in the health care system as a right of the woman, within the scope of the obligatory health insurance scheme. Although there have been attempts for introduction of regional organized screening to a specific population group in the 1970'ies, the screening program in general was opportunistic and was not population-based. The costs of the screening for the woman were covered by the health insurance only when done by their primary gynecologist, and were covered by out-of pocket payments when done in the tertiary health care organization. This type of program resulted with a coverage of ~10% of all women annually (Gynaecology clinic public presentation 2007).

In 2004 under a pressure of the "parliamentary group for equal opportunities" and few NGO's in the country, which are active in the field of women's rights, the cervical cancer screening was included as a basic right of all women in Macedonia regardless of their health insurance status, and represented one of the "measures and activities for early detection and prevention of the diseases of the female reproductive organs" (Official Gazette of the Republic of Macedonia 2004). As such, it provided the legal basis for creating two special programs for cervical cancer and breast cancer prevention.

Having acknowledged the coverage of the screening in Macedonia as low, and under the influence of the WHO "Health for All" strategy, emphasizing the

[1] The citizens which do not possess health insurance, or their insurance fees are not regularly paid by their employers are regarded as *citizens without regulated health insurance*. Legally in Macedonia the employer has the obligation to pay the health insurance contributions for the employed citizens (Official Gazette of Republic of Macedonia 2000).

importance of cancer control (WHO 1999), as well as the WHO EURO Regional Strategy on Sexual and Reproductive Health (WHO 2001), the Macedonian Government in 2005 has designed a special - vertical program, "aimed at promotion of early detection of pre-malignant and malignant lesions of the cervix, with the objective of timely management, further treatment and ultimately decrease of deaths resulting from cervical cancer" (Official Gazette of the Republic of Macedonia 2007, p.3). Only in 2007 this program received public attention. The public promotion element of this program was combined with the promotion of the program for "breast cancer prevention".

The special program for cervical cancer screening, publicly recognized as "the campaign", continued in 2008, and is planned for 2009 as well. In 2007 and 2008 it consisted of two elements: free PAP tests offered through primary and tertiary health care facilities, and awareness-rising through information and education campaign (Official Gazette of the Republic of Macedonia 2007a). The primary target group of this program are the uninsured women, but mechanisms are envisaged for spreading the message among the insured women as well. This program remains the first and only nation wide campaign for cervical cancer prevention in Macedonia, and it is an attempt to closely define the overall basic principles of the national strategy for cervical cancer screening. However, until 2009 it did not show a shift of the screening modality towards organized and population-based system, and the preliminary review of the publicly available documents and reports could not identify provisions for quality assurance of the process. The program for 2009 entails a component of pilot organized screening in one town in Macedonia.

The HPV vaccine as the main feature of the primary cervical cancer prevention activities, is available on the market in Macedonia since 2007, and in May 2008 the vaccination has been addressed as a public health strategy for cervical cancer control. In October 2008, a campaign was launched for vaccination of girls aged 9-26. This was envisaged as a non-obligatory voluntary vaccination, added in the immunization program of the Ministry of Health. The estimated coverage was ~2% of the female target population (Official Gazette of the Republic of Macedonia 2008). The vaccine is included in the regular immunisation schedule for 2009 for all girls aged 12.

Macedonia has been marked as one of the countries that have started the health sector reforms at a very slow pace accelerating it to enormous speeds in the past several years; in such a very changing environment, often times overlaps and gaps are easy to happen, resulting in parallel programs, activities and events that put extra burden on the weak health budget of the country. Indications exist that the national cervical cancer related policies and programs are not formulated following the best-practice and the existing evidence in the field. Lack of integration of the policies and programs with other relevant policies in the country (the health insurance policy for example) and lack of coordination and communication among the stakeholders in the process seem to be the major problems. This leads to a need for identification and analysis of the information

and coordination gaps between the different cervical cancer prevention related national strategies, action plans and implementation arrangements; this includes different documents prepared for and agendas within the public health and other relevant sectors, as well as managerial and coordination activities, which will bring to light both advantages and challenges that need to be overcome for the integrated and more efficient addressing of the complex health issue of cervical cancer prevention.

RESEARCH QUESTION

How the current national policies and programs related to cervical cancer prevention in Macedonia are being designed and implemented to provide meaningful public health benefit (reduction of incidence and mortality)?

OVERALL OBJECTIVE

The objective of the research is to perform a comparative analysis of the national cervical cancer prevention policy with the processes and programs related thereof, by characterizing the basic organisational context of the cervical cancer prevention programs in Macedonia, and through the frame of reference of the international guidelines and recommendations.

SPECIFIC OBJECTIVES

The study has focused on an investigation and analysis of the components of cervical cancer control which fall under the scope of prevention activities (primary prevention and early detection through increased awareness raising activities and screening programs), and has given only a short description of the existing policy and basic infrastructure for diagnosis, treatment and palliative care for advanced disease, as essential complementary elements of a comprehensive cervical cancer control program (WHO 2006, p.20).

The analysis of the primary prevention and early detection of cervical cancer, including the health education and counselling activities has been performed in the following dimensions:

Context assessment: identification and review of the historic and current national policies, guidelines and recommendations, as well as international recommendations and related documents;

Empirical assessment: characterization and providing deeper understanding of the delivery and organizational structure of the national programs and actual practices;

Comparative analysis of the findings from the empirical assessment in correlation with the national and international policies and recommendations, with the aim of identification and assessing the discrepancies between the expected and the actual directions of the program, analysing its strengths and weaknesses, uncovering obstacles, barriers and/or unexpected opportunities.

METHODOLOGY

Study design

This study followed a predominantly qualitative methodological approach, in a form of formative evaluation of the design and implementation of the programs, followed by a comparative analysis. A comprehensive assessment was conducted using **field research**, which included the following techniques for gathering both **primary** and **secondary data**:

1) In-depth interviews; 2) Document research; 3) Observations

The qualitative methodology, with its inductive approach emphasizes developing insights out of the data collected and gives researchers rich information about the complexities of the organizational context and social processes in specific settings and wider social and policy environment (Neuman 2003). Although the findings obtained by the qualitative methodologies are usually not statistically representative of the population under study, they provide basic understanding of a given situation that can then direct subsequent quantitative investigation, if required (Neuman 2003; Esterberg 2002). Formative evaluation as a technique was chosen while it has been identified as "responsive to the dynamic context of a program, and as one which attempts to ameliorate the messiness that is an inevitable part of complex, multi-faceted programs in a fluid policy environment" (European Communities 1995-2008). The strength of this technique is that "it provides a rich picture of a program as it unfolds. It is a source of valuable learning not only prospectively for the program but for future programs as well" (European Communities 1995-2008). However, as mentioned in the Evalsed resources (European Communities 1995-2008), this type of evaluation requires support from the stakeholders, which may be withdrawn "if the findings expose weaknesses in program design or implementation, especially where the organizational culture is one of blame and discourages innovation or learning from mistakes". Also, the reliance on qualitative methods "may fail to meet the expectations of some stakeholders for robust quantitative measures of progress". These represented the possible caveats, which were dealt with by careful explanation to the study participants of the purpose and advantages of this kind of research. Another disadvantage of the design of this study is that the qualitative field research methods as such produce vast amount of data and "are heavy in their use of time and evaluation expertise, both at the data gathering stage as well as in the analysis" (European Communities 1995-2008). This was the case with this study as well, and it was alleviated by careful time-planning of the research activities.

Research location

Since the capital of the country – Skopje is the biggest town in Macedonia with approximately 25% of the population living there, the main part of the study was conducted in Skopje. Two other towns – Prilep and Kumanovo, were included as well, as towns – representatives of the regions with middle and low relative GDP respectively (State statistical office 2008a). The involvement of 3 towns in the study was not done in order to obtain representativeness of the study, but to provide more information on the process which was investigated, in a different socio-economic environment.

Data collection

The data collection techniques used in this study (as mentioned above) were identified as most suitable for "obtaining insightful and rich data on complex issues" (Bowling 2002, p.131).

In-depth interviews

The technique of unstructured in-depth interviews was used, as it was identified as having the advantage to probe more complex issues and the answers could be clarified while performing the interview. The interviews were topic based and an interview schedule with the checklist of the topics to cover was used. As the interviews were unstructured, the order and content of questions in the interview schedule was not strictly followed, and was adapted to the dynamics of the conversation. The questions were open-ended and exploratory, aimed at uncovering the processes by which the program takes shape. The questions were not pre-coded. A brief structured list of questions about the respondent's education, occupation and professional background was included. All respondents were asked for a permission to tape-record the interview, with the explanation that in this way the subsequent detailed analysis would be facilitated, and the "memory bias" would be avoided. When the respondent gave permission the interviews were tape-recorded, transcribed and entered to computer later on. When the respondent denied tape-recording, interview-notes were taken, which were transcribed immediately after the interview took place, as an attempt to minimise the impact of the "memory bias". Field-notes were also taken in a form of condensed description of the research activity, to ensure that much detail about the interview environment were captured and recorded.

The in-depth interviews were conducted among key informants pertinent to the field. The **informants** represented different stakeholders in the process to be analysed:

- primary gynecologists (3 interviews),
- secondary gynecologists (4 interviews),

- tertiary gynecologists (3 interviews),
- professionals from the "mother and child care" department (2 interviews),
- histo-pathologists (2 interviews),
- epidemiologist (1 interview),
- policy and program makers at central level (2 interviews),
- NGO-worker, involved in women's rights (1 interview).

Emphasis was placed on collecting both current and historical information on the following:

- Identification of the available and availed **resources** within the health system of the country, which are disposed for the activities related to primary prevention and early detection of cervical cancer i.e. the responsible institutions and professionals (management and health-care team);
- **Basic design of the prevention programs:** screening and vaccination modality, target group and age range, screening interval, the geographical and demographic coverage, integration of the programs, strategies for sustainability of the programs, historically important changes in screening organization;
- **Financial** aspects and arrangements;
- **Promotion strategies** of the programs: methods to increase coverage, counseling of patients, information and education of the citizens, cultural sensitivity of the media messages, education and training of health professionals;
- **Follow-up** of cases and management of screen positive women; **ethical** issues; **communication** between stakeholders,
- **Process and performance measures:** the health information and quality assurance system; the reporting system, monitoring and evaluation, the indicators used, use of evidence based medicine, protection of patient's rights.

The content of the individual interviews was tailor-made in accordance with the respondent's professional background, still in the framework of the above mentioned categories.

While conducting the interviews certain principles appropriate for the qualitative methodology were followed, including:

- Using combination of questions on: experiences and behaviours; opinions and values; and factual knowledge;
- Revealing as little personal information as possible about the interviewer, especially when asked to share an opinion on a topic;

- Avoiding leading questions which make assumptions about the respondent or his/her replies;
- Using probes, to check for the consistency in the replies; the probing was done in a non-leading manner, avoiding negative probes;
- Adopting a neutral, non-judgmental manner towards the experiences and perceptions of the respondents, showing neither approval nor disapproval;
- Allowing and promoting the respondent to give additional input to the interview, apart of the pre-planned topics, in case he/she considers it as an important contribution.

Document research

The document research entailed analysis of **public official documents** and **media accounts.** The researched public official documents were: government policies and strategies, national and international recommendations and guidelines, public demographic and epidemiological records produced by the government and hospitals, program management documents, official public epidemiological reports, statistical sources, program reports, NGO reports and analysis. The media analysis was diachronic and included analysis of the national newspapers, magazines, TV and radio programs, electronic texts. The findings from the documents research were triangulated with the ones from the in-depth interviews and the observations.

Observations

The observations were chosen as a part of the triangulated research methodology. They were performed in a natural setting and the focus of the non-participatory observations were the **public gatherings**, which took place as part of the national cervical cancer prevention campaign **(workshops, meetings)**. The gatherings happened in more towns in Macedonia, in the medical centers and other locations, in urban and rural setting. However, for logistic purpose the observation venue was limited to public gatherings which took place in Skopje. Different stakeholders involved in the process – both policy makers and members of the medical community, were present at the public gatherings. The primary aim of the observations was to obtain richer insight of the promotion strategies of the programs among the population, but they revealed valuable information on the target population, the coverage of the programs, cultural sensitivity of the messages, communication among the stakeholders, epidemiological information. The observations were non-participatory and unstructured / qualitative. The data were gathered through a pre-prepared check list and guideline on the topic. Additional information was also noted during observation. The events were audio-recorded directly as they occurred and supplementary field-notes were taken. The gathered data were transcribed.

Gaining access to the desired setting was obtained through negotiations with the organizers of the public gatherings.

Sampling

For the field research the method of **purposive sampling** was used: "a deliberately non-random sampling, which aims to sample a group of people, or settings, with a particular characteristic,… selected because they have knowledge and diverse experiences that are valuable to the research process" (Bowling 2002, pp.187-188). This method for recruitment was complemented with **"snowball" sampling**, whereby respondents were asked to refer to peers and other members of the social community. As "the aim of all qualitative methods is to understand complex phenomena and to generate hypothesis, rather than to apply the findings to a wider population" (Bowling 2002, p.187), the representativeness was not the prior aim of the study and the study sample was of rather small range. The **eligibility criterion** for inclusion in the study was the involvement in the process of prevention of cervical cancer in Macedonia. Eighteen interviews and three observations were made. The observations were based on the preliminary information obtained about sites, type and time of the topic discussion (workshop and meeting). The adequacy of the sample size was attained when sufficient data has been collected and saturation was reached (the major trends began to recur) (Pope, Ziebland and Mays 2000; Neuman 2003, p.439). It was concluded that the data obtained with the observations reached saturation early during the research process, so their number was limited to three. In contrary, the interviews kept providing broader spectrum of information. The criteria for inclusion in the study, as well as the sample size, were intentionally not very specific and not strictly planned in advance, as it was assumed that, taking in account that the nature of the research is qualitative, it would limit the realization of the research and the findings obtained would be rigid.

The research units were:

Location	Research unit
Skopje	12 interviews and 3 observations
Prilep	3 interviews
Kumanovo	3 interviews

Data processing and analysis

Initially the field-notes, the recordings and the other collected data were transcribed in ".doc" format, giving the documents coded names. The code of each document's name was designed to identify the source of data, the venue of

research, and in case of interviews – the professional background of respondent.[2] The further **processing of the data** was computer-assisted, using the qualitative computer software "Atlas.ti". The textual data was explored using **content analysis** to identify the main issues, which were categorised and indexed (coded). The main **analytical categories** (thematic groups) under which to organize and compare data were: 1) Basic design of the prevention programs, 2) Detailed organisational issues and 3) Process and performance measures. The concepts and issues included in these thematic groups were pre-defined, but also others were inductively generated and developed alongside data collection (Neuman 2003, p.176). All the data relevant to each category and concept were identified, examined and compared with the rest of the data. This interim analysis guided subsequent data collection and refinement of the inquiry questions (Pope, Ziebland and Mays 2000; Neuman 2003, p.440). The inductive approach to the construction of the inquiry questions led to the need for their regrouping in the reporting phase, in a way which would be most adequate for preparation of the report.

Finally, using the developed analytical categories, **the analysis** of data was conducted by making comparisons of the findings, both internally among the gathered empirical evidence, as well as externally – with evidence from related documents and international guidelines as an "ideal type" (idealized model) (Neuman 2003, p.450). Consequently, the organization of the data in the "Results" section follow a pattern in which the inquiry questions grouped in analytical categories are analyzed in three **dimensions for comparison**: 1) context assessment – the national policies and "theoretical" design of the programs as presented in the official national documents; 2) empirical assessment - the actual implementation of the programs in practice; 3) the international context - policies and guidelines for cervical cancer prevention.

Validity of results

The internal and external validity of the results was assured with the following measures:

- Triangulation of the results from the different methods used;
- Performing checks for internal consistency of the gathered data, by comparing their plausibility for interrelated items (i.e. "personal invitation" and "population-based screening") and by using probes during the interviews;

[2] Some of the referred sources in the text related to the field research – the interviews, the observations and the media accounts, are followed by citations. The citations are indicated using the coded documents names followed by a small letter. The full description of the codes is included in the **Annex 1**, and all citations referred to in the text are included in **Annex 2**.

- Avoiding leading questions and placing personal judgements and opinions during the field-data collection process, as a mean to diminish the potential for "interviewer bias";
- Avoiding to cite or use for analysis an information which is provided by only one source of information;
- Trying to obtain consent for tape-recording the interviews as much as possible, and transcribing the notes in a short time period after the interview took place, so that the "memory bias" could be avoided.

However, as an identified threat to the validity of the results is the "social desirability bias" during the interviews, and the respondent's desire to provide "true" answers and over-report "good" behaviour. There were certain topics, as for example the counselling activities which happen in the doctor's office, for which it was very hard to check for the internal consistency, as the physicians are very well aware of what would be the best practice. The best way to check the validity of their answers would however be a patient-oriented survey, which was beyond the scope of this research. The possibility for "social desirability bias" was taken carefully into account when presenting the results of the field research, at first place by verification of the answers through their triangulation with information from other sources, but also by paying attention to the whole interview, the setting in which it was performed and the background of the respondent.

ETHICAL ISSUES

This study was not intended to have a clinical component and no biological specimens were taken from study participants. However, the research proposal received an approval from the ethics committee of the Medical Faculty, the University "Ss Cyril and Methodius" in Skopje, as an accredited education and scientific institution. According to the legal framework in Macedonia, ethical approval from additional institutions was not required to conduct the study.

While Macedonia does not have its own codes for research ethics, the study complied with the ethical guidelines of international organizations such as the American Sociological Association (1999), the Statement of Ethical Practice of the British Sociological Association (2002), the Good Research Guidelines of the Medical Research Council (2000).

The field research followed the principles of confidentiality and privacy, and no information on the identity of the study participants was tape-recorded, although they are known to the researcher. The study participants were given written information and explanation about the aims and objectives of the study, the principles of confidentiality and anonymity, the instruments used, the dissemination of the results. They were informed that they are free to withdraw at any time. Subsequently they were asked to sign a written informed consent prior to the interview. In the cases of direct observations where the researcher did not bring out information from specific individuals, but rather record activities and characteristics in a given venue, no informed consent was requested. No remuneration / incentive was provided to the respondents.

RESULTS

Resources

The cervical cancer control activities in Macedonia are performed through all levels of health care, mainly provided by the gynecologists, which work in primary, secondary and tertiary health care facilities. The country has a strategy for financing the specialization of physicians only in case they are employed in a public health care institution.

The services for "health protection of women" (in the text to follow referred to as "women's health services"), are an integral part of the primary health care in Macedonia. They are performed by the primary gynecologists. The total number of gynecologists in Macedonia is ~300, or ~15/100.000 total population; approximately half of them are primary care gynecologists (HIF 2008; I_06_PG_SK_a). This indicator is in line with the EU average (WHO 2009).

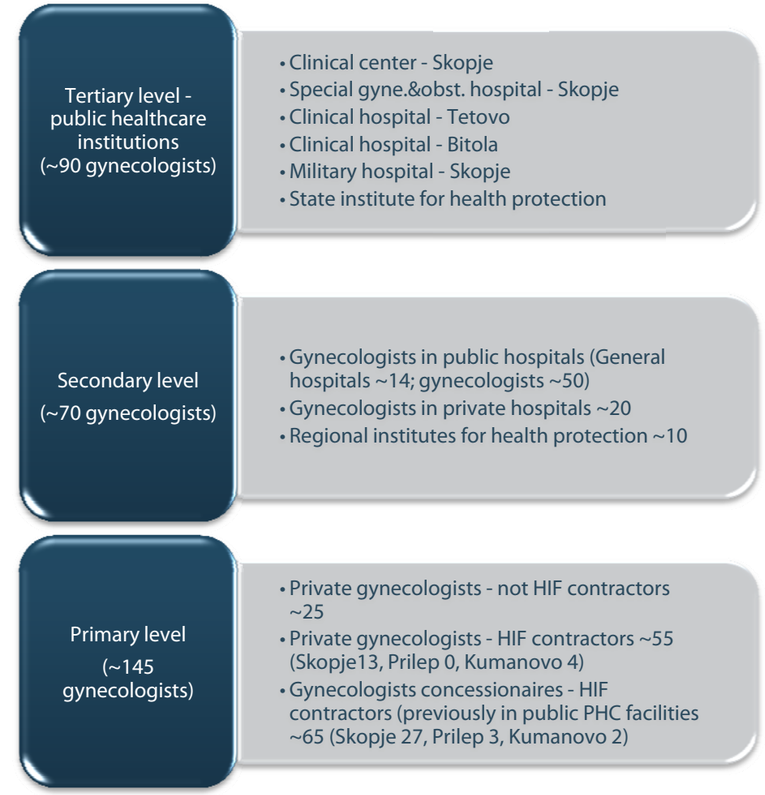
The primary focus of the cervical cancer early detection activities is and has been historically placed in this part of the system. The gynecologists are the only accredited to take PAP smear. The main responsibility for the counseling activities of the women falls at the women's health services. All activities associated with the screening happen in the doctor's offices.

The primary gynecology practice in Macedonia is completely private. One part of the gynecologists has been originally private, and the others are concessionaires. The term "concessionaires" refers to the physicians which until 2007 were working in the public sector, and after the reforms and the privatization of the primary health care took place, they legally became private entities/enterprises, but continued working and using the existing public infrastructure (offices, equipment), paying a small rent to the state. While all concessionaires work with the health insurance scheme, some of the originally private gynecologists do not have contracts with HIF signed.

The secondary health care facilities are mostly public, located in the towns throughout the country. There are only two secondary level hospitals, which deal with gynecology practice located in the capital; they are private and do not have contracts with the HIF for the services related to cervical cancer prevention.

The tertiary health care in Macedonia is completely public and located in the capital and two other towns in the country. The distribution of the gynecologists and the health care institutions and facilities which perform activities related to cervical cancer prevention in Macedonia is displayed in Figure 1.

Figure 1 - Review of the health care services at primary, secondary and tertiary level, related to the cervical cancer prevention activities.



Sources: (SIHP 2005, p.69; HIF 2008; the interviews)

There are ~650.000 women aged 20-69 [3] (2002 data) (State statistical office 2003; IARC 2002). It is considered that ~10%, or ~65.000 women are either not covered by the health insurance scheme, or their contributions are not regularly paid by their employer (Official Gazette 2007a). The insured women are obliged

[3] For the needs of this research, this age group is referred to as a target group for gynecology practice, as it taken as the denominator in the definition of the indicator "Women who have had PAP smear" in the WHOSIS database (WHO 2009).

to select their primary gynecologist in order to be entitled to the insurance benefits at the level of "women's health services".

There are ~ 2.100 women from the target group per gynecologist, or ~ 4.500 per primary gynecologist. However, the burden to the primary gynecologists within the insurance scheme in reality is lower, as many patients, although insured, use the private services.[4] It is identified that some of the public secondary and tertiary level institutions use the opportunity to perform private "women's health" services, and make gynecological examinations as if they were at primary level, without a referral (I_03_SG_PP_a; IN_04_SG_PP_a). As a result of these possibilities, but also as a result of the lack of awareness of the women for the benefits of the "selected primary gynecologist" within the framework of the health insurance scheme, many of the insured women in Macedonia haven't officially selected their primary gynecologist, and bypass the services within the insurance scheme.

There are evident regional differences in the geographical distribution of the gynecologists, especially the primary ones. If the national average is 4.500 women per primary gynecologist (in case all women would have selected one), then in Prilep, as one of the towns included in this study, the average would be as high as ~8.000, and in Kumanovo ~5.800 (SIHP 2005a, p.62 & 20; HIF 2008; I_15_SG_KU). It is worth mentioning that the number of gynecologists in the secondary practice in Prilep has fallen by almost 40% in the past 3 years (I_05_SG_PP_a). To illustrate the regional distribution inequalities of the primary gynecologists among regions, in 2005 the public primary gynecologists which later became concessionaires had in average 14,5 visits/day/doctor, in a range of 4 to 36 visits/doctor/day in different health regions. In Kumanovo there were 34 visits/day/doctor, in Prilep – 13 visits/day/doctor, and in Skopje – 16,3 visits/day/doctor (SIHP 2005, p.84).

The pathologists, as an important chain in the early detection and diagnosis of the cervical cancer, until recently were mainly located in the public secondary and tertiary health care facilities throughout the country. However, the trend of opening private laboratory practices which perform cytology services is increasing (I_06_PG_SK_b), and some of them already have contracts with the HIF (I_18_PG_SK).

There are ~25 physicians histopathologists [5] in Macedonia, which are trained in cyto-technniques. The biggest cytology laboratory is in the Gynecology Clinic of the Clinical Center in Skopje. This laboratory has one cytologist and 10

[4] "Private services" in this sense are all services paid by "out-of-pocket" money, and not covered by the insurance scheme. These can be done in private and public health care facilities at all levels, in institutions which do not have contracts with the HIF, but also in institutions which are HIF contractors.

[5] There is no specialization in cytology in Macedonia. The physicians which review the cytology samples are specialists in hystopatology, which are additionally trained (non-degree) in cytology techniques.

cytotechnicians, responsible for triage of the samples, and performs 60.000-75.000 samples annually (Gynecology clinic public presentation 2007), which represents the majority of the total number of samples in the public cytology laboratories. Arbitrary, it performs ~90% of the total samples' review, but this is only an estimation, as there is no national comprehensive PAP screening database, which would help in providing more precise data (IN_14_PAT_SK; I_09_TG_SK). The biggest histology laboratory is at the Oncology institute of the Clinical center in Skopje. There are cytology laboratories in seven bigger secondary general hospitals in Macedonia, which have only pathologists. As there are no cytotechnicians employed there, the pathologists perform both triage and diagnostics of the PAP smears (IN_14_PAT_SK_a). These laboratories deal both with PAP samples and biopsy samples (IN_04_SG_PP_b).

The cervical cancer screening is done using the conventional cytology technique. However, in 2006 the liquid based cytology was introduced, but only in the cytology laboratory of the Clinical center in Skopje. It covered 3% of the examined samples (Gynecology clinic public presentation 2007). In 2007 this technique was discontinued, although the equipment was bought and training for primary gynecologists was performed (I_09_TG_SK_a; I_06_PG_SK_c).

The colposcopy is a routine technique in the gynecological facilities in Macedonia. Most of the private facilities and all tertiary facilities have a colposcope. The gynecologists concessionaires and the other gynecologists in the primary practice which did not have one, very recently received a grant from the Health Insurance Fund, in the amount of ~1500 EUR, specially assigned for purchasing a colposcope (HIF 2007; I_06_PG_SK_d). However, not all secondary hospitals throughout the country have a colposcope, as is the case in the General hospitals in Prilep and Kumanovo. Some physicians do not regard this as being necessary for performing the secondary gynecology services (I_03_SG_PP_b; I_15_SG_KU_a).

The HPV DNA test, called "HPV type determination" is performed in Macedonia as a diagnostic procedure using PCR technique. There are five laboratories within the public health care and scientific institutions (two in the Clinical Center, one in the State Institute of Health Protection, one in the Macedonian Academy of Sciences and Arts and one at the University). All of them are located in the capital – Skopje.

The diagnosis and treatment activities for pre-cancerous and cancerous (Carcinoma in situ) lesions of the uterine cervix are performed in secondary and tertiary level hospitals, with a referral from the primary health care. The "cervical conization", as the most common therapeutic procedure for these indications is performed both in secondary and tertiary hospitals (the Clinical center in Skopje and the general hospitals throughout the country), and is used as a diagnostic tool as well. Laser vaporization is also used for treatment of pre-cancerous and cancerous lesions. The treatment of invasive and microinvasive cancer (surgery, radiotherapy and chemotherapy) is done in tertiary level hospitals, mainly in the Gynecology Clinic of the Clinical center in Skopje.

The State Institute for Health Protection, with its ten branches - Regional Institutes for Health Protection, is a scientific public health institution, responsible for health promotion activities including disease prevention, collection and analysis of health status and care-related data, performance of environmental health risk assessments, surveillance of communicable and non-communicable diseases etc. (Gjorgjev et al. 2006). This institute is involved in the planning of the immunization activities in the country, and performs some of the vaccinations, including Influenza and the HPV vaccination (Official Gazette 2007b). The regular immunization activities, within the framework of the immunization schedule are performed within the pediatric primary health care services.

Important chains in the preventive services are the patronage nurses, which perform services based on family needs, primarily for postpartum visits to the mothers and infants. There was an initiative in the past, within the framework of the "Mother and child health protection program" for extension of the activities of these patronage nurses, and their involvement in the preventive and therapeutic activities related to cardiovascular disease, TB and cancer. This initiative was discontinued after a certain period, and the data were not summarized at national level (Gjorgjev et al. 2006; IN_07_MC_SK_a).

Basic design of the prevention programs

The resources described in the previous chapter are disposed for programs and activities for early detection (screening) and primary prevention (HPV vaccination and risk factors control) of cervical cancer in Macedonia.

Cervical cancer screening

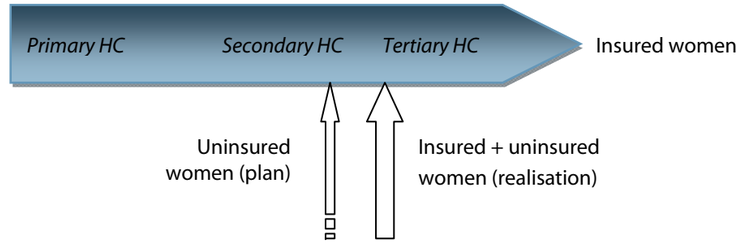
The processes related to the early detection of cervical cancer can be best described using the "horizontal – vertical" scheme.

The **horizontal processes** would represent the activities which are integrated in the health care, through the system of primary, secondary and tertiary institutions and their well established roles and responsibilities. While the primary level gynecologists, organized as "women's health services", act as the gatekeepers of the system - deal with the majority of the women in need of service and have the responsibility for their counseling, the secondary and tertiary level facilities deal with cases with referrals and are responsible for the diagnosis, treatment and palliative care. In case the woman is covered by the health insurance and has the insurance fees regularly paid, she has a right to use these services under the insurance scheme. This is the case with the estimated ~90% or ~580.000 women in Macedonia (Official Gazette of the Republic of Macedonia 2007a).

The "Program for early detection and prevention of the diseases of the reproductive system in the woman in Republic of Macedonia" (in the text to

follow referred to as "the Program" or "the campaign" [6]), brought up by the Government in 2005, can be considered a **vertical program**. The term "vertical program" in this context does not refer to a program where the health care providers and resources are devoted to only one health care service. The term indicates that the program in question is planned and budgeted separately than the integrated services, and for the same type of care as in the integrated services – different health care levels and logistic facilities are used, thus resulting in changing of the staff roles and responsibilities during the course of the program and transforming the access to services by the clients, in relation to the regular one. The screening services according to the Program in 2005 and 2006, although separately planned, were envisaged to follow the system of primary-secondary-tertiary health care as described above. However in 2007 and 2008 there was a switch in the policy and it was decided that the screening services are delivered in the secondary and tertiary level gynecology facilities. The inspection of the smears was performed only in the cytolaboratory of the main tertiary level institution: the Gynecology clinic in the Clinical center – Skopje, which is being considered as a reference laboratory. The estimated 10% of the women (~65.000) in Macedonia, which do not possess health insurance at all, or do not have the insurance fees regularly paid are entitled the right to cervical cancer early detection activities under this Program. However, although these services in 2007 and 2008 were officially envisaged (as per the documented program design) to be affordable only for the uninsured women, in practice they were available to all women, regardless of their insurance status (confirmed by all interviewees). The position of the vertical program in relation to the integrated services for cervical cancer early detection is visualized in Figure 2.

Figure 2 - The target groups of the cervical cancer early detection activities at different levels in 2007 and 2008



The programmatic guidelines as such, documented and officially published, are available only for the vertical Program. They entail provisions on the target population, age group and screening interval, responsible institutions for

[6] This program is also referred to as "the campaign" by the professional community and the public in Macedonia.

coordinating and delivery of the screening services, strategies to increase coverage, financial arrangements. This program primarily describes the activities focused at the uninsured women, but some of the provisions entailed, refer to the integrated screening services as well, mainly in the area of defining the age range and screening interval. The "Information and Education" element which is part of this program, refers to the complete population of Macedonia as well (Official Gazette of the Republic of Macedonia 2007a). The following elements are not described in the published programmatic guidelines: procedures for maintaining requisite quality, reporting on performance and results, guidelines and rules defining standard operating procedures, a quality assurance structure and a means of ascertaining the population burden of the disease. "Such elements generally provide for supervision and monitoring of most steps in the screening process" and are essential prerequisite for the program to be regarded as organised (European Communities 2008b, p.15).

Both the "program screening", as well as the screening within the horizontal level services, are fully opportunistic, initiated by the patient or the gynecologist, and the doctors do not have an obligation to send invitation letters to their patients.

The target age for the cervical cancer screening, at all levels and no matter whether in the integrated services or during the campaign, as indicated in the Program, are the women aged 19-65 (Official Gazette of the Republic of Macedonia 2007a). However, the research identified that the physicians do not limit these activities within this age range, and they screen even younger women, after a certain period from the sexual debut. The explanation of this habit, given by the physicians, lies in the belief that the average age of onset of sexual relations in the youth is usually lower than 19, therefore it is of 'no damage' if they did the Papanicolau even at younger age (IN_02_PG_KU_a).

The screening interval, as documented in the Program should be 5 years, both for the uninsured and the insured women, and the coverage aimed for in the course of 5 years is 100 %:

> According the WHO recommendations the cervical cancer screening is made within an interval of 3, 4 or 5 years. … In Republic of Macedonia the screening will be accomplished within a period of 5 years, and the target group will be all women aged 19-65. The program will cover the women which possess health insurance, but also the ones without their insurance being regulated. The total No. of women aged 19-65 is 640.000.
>
> The screening for the insured women will be done by the primary gynecologists, within the basic health services package…and out of the total No. of 576.000 insured women, annually the primary gynecologists should perform screening at 115.200 women…
>
> The screening for the women who do not possess health insurance or do not have the insurance fee regularly paid, will be performed

> according to this program in the General hospitals, Special Clinics and the Gynecology clinic. These women count for 10% or 64.000 women. In order this number is embraced within a period of 5 years, it is necessary that 12.800 women are screened annually in the gynecologic departments of the hospitals" (Official Gazette of the Republic of Macedonia 2007a).

However, in practice the gynecologists perform the opportunistic screening i.e. PAP examination, at an interval of **one year** regardless of the age of the woman, and both within the framework of the integrated "women's health" services and as part of the campaign. This is confirmed with the interviews with all informants, the media reporting and the observations. Some gynecologists, during the interview, expressed the opinion that broadening the interval even to 3 years would be too risky (I_09_TG_SK_b; IN_03_SG_PP). Other informants made a distinction between the opportunistic screening and the organized screening with this regards. They agreed that broadening the screening interval up to 3 or 5 years would be feasible, but only if the approach is organized (I_10_TG_SK_a). In the case of Macedonia, where the approach is still completely opportunistic and the coverage is recognized as low, it would be too risky to broaden the interval, since "we could loose even the women which currently take the opportunity to initiate PAP examination" [7] (I_10_TG_SK).

HPV Vaccination

With regards to the HPV vaccination, in 2007 the 4 valent vaccine SILGARD, product of MSD was registered and entered the Macedonian market, while at the end of 2008 the vaccine CERVARIX by GSK was registered. In 2007 the vaccination was completely voluntary and paid out-of-pocket by the interested citizens. In May 2008, there was a decision by the Government that the vaccination, as a "non-obligatory", will be financed through a special program budget of the Ministry of Health, therefore free of charge for the girl to be vaccinated (Official Gazette of the Republic of Macedonia 2008). This program was going on for less than one month and covered 4.500 girls aged 9-26 on the "first come-first served" basis, regardless of whether they are insured or not. No information for the HPV infection status of the girl to be vaccinated was required (IN_01_EPI_KU_a). The Ministry of Health procured all the doses for the 4.500 girls. The institutions performing this program are the Regional Institutes for Health Protection throughout the country, two tertiary health care facilities, and few private primary health care institutions, which fulfill certain pre-determined criteria by the Ministry of Health (Ministry of Health 2008). This was regarded by some as a

[7] Some informants used the term "screening" only in the case of organized screening. They denied that there is any "screening" in Macedonia, taking in account the current organization of the cervical cancer early detection activities in the country.

strategy for "promotion/awareness raising regarding the possibility of immunization" (M_A1_Vacc._27.11.'08), and by others as a "catch-up" campaign prior to the announced "population based" routine program for HPV vaccination, which is to be launched in 2009 (I_10_TG_SK; Vlada 2008). This program was accompanied with a strong media promotion, resulting with an unexpectedly high interest for the possibility for vaccination: only one month after the onset of the campaign, and after the available vaccines were already administered, there was a list of another 10.000 girls, interested to be vaccinated.

The vaccine is included in the immunization schedule for 2009 in 12 years old girls (Official Gazette of the Republic of Macedonia 2009).

Table 3: Stakeholder analysis

Stakeholder	Stakeholder role
Primary healthcare practice (women's health services) - physicians gynecologists	- Basic gynecologic check-up - Taking PAP smears and their preparation for cytological analysis - Taking samples for HPV DNA test - Performing colposcopy - Counseling activities - Referring to the secondary and tertiary level services - Performing follow-up activities
Secondary healthcare practice – physicians gynecologists	- Taking PAP smear, HPV DNA test, and colposcopy - with referral from a primary gynecologist when working under the insurance scheme; without referral – when performing private services - Taking biopsy samples - Treating pre-cancerous and cancerous lesions (Ca-in situ)
Tertiary healthcare practice – physicians gynecologists	- Taking PAP smear, HPV DNA test, and colposcopy (with referral from a primary gynecologist) - Taking biopsy samples - Treatment of all stages of pre-cancerous and cancerous lesions; treatment of cervical cancer; palliative care - Involvement in the design of the "screening campaign" (the Clinical center as the biggest tertiary level facility) - Involvement in the realization of the "screening campaign" and the vaccination campaign (the Clinical center and the Special Gyn&Obst hospital)
Histopathologists – cytologists	- Review of the cytology (PAP) and histology (biopsy) samples - Reporting back to the physicians
Institute for health protection of mother and child	- Co-ordination of the awareness raising campaign

Stakeholder	Stakeholder role
Institutes for health protection	- Involvement in the awareness raising campaign - Performing the HPV vaccination campaign - Data and information collection and statistical analysis
NGO's / women's lobby / parliamentary equal opportunities commission	- Involvement / co-ordination of the awareness raising campaign
Ministry of Health – Department for preventive care	- Design of the "cervical cancer prevention campaign" and the "HPV vaccination" campaign - Observation of the progress and performance of the campaign - Gathering of the sites' reports and compiling the integrated report

Financial aspects

To explain the financing of the cervical cancer prevention cervices, a distinction will be made in financing:

- the integrated screening services, conducted through the primary level health care;
- the vertical screening services performed through the Program;
- the HPV vaccination.

After their privatization the **primary health care** facilities which do have contracts with the HIF, and the gynecology service as a part thereof, are financed through a system of capitation. The **capitation** point in the time being amounts to ~0,8 EUR / patient / month. For each primary gynecologist, the HIF envisaged an optimal number of 2.000 patients per gynecologist. This is reflected in the capitation amount, which decreases for ~30% for each 1.000 new patients. The capitation points are in one part (70%) paid as a fixed payment by the HIF per insured woman, and the other part (30%) is paid according to the achieved objectives by the contracted health care provider. The objectives constitute a set of predetermined categories, as for example: number of prescriptions, number of referrals to higher level of health care, preventive medical check ups / early diagnosis of cardiovascular diseases, cancer etc. All of these categories are measured quantitatively. Performing PAP test to 25% of the patients which selected the particular gynecologist, is included in these categories, and brings most of the extra capitation points (HIF 2008b). The policy is that the following year, another 25% of the women should be screened in order the next year's target is reached, thus stimulating two-yearly interval of PAP-screening. However,

no reward is envisaged in case the gynecologist performs PAP tests to more than 25% of the patients (I_06_PG_SK_f). Performing colposcopy to all women with "positive PAP test"[8], and organizing of education workshops on the topic of sexually transmitted infections for the patients aged 14-26 are also in the set of objectives for the variable part of the capitation points (HIF 2008b).

The reference price of the PAP test which the HIF pays to the laboratories as part of the integrated services is ~10 EUR (Official Gazette of the Republic of Macedonia 2008a).

The services done at a primary gynecologist which is HIF contractor are free of charge for the patient. However, in case the service involves a higher level institution, as for example a laboratory assessment, than the patient pays co-payment only for the part which is performed in the higher level institution. Consequently, the PAP examination, as a part of the primary level check-ups which involve laboratory assessment are paid with co-payment of approximately 10% of the service, which means that the patient should pay ~1 EUR co-payment for the PAP examination, regardless of whether the PAP test was done with medical indication or for a routine screening. As confirmed by the gynecologists, as well as a representative from the HIF, the number of PAP tests performed with this level of co-payment is not limited by the HIF. An exemption of this rule is one PAP test performed in a year, which can be completely free of charge for the patient, if the sample is assessed at the cyto-laboratory of the Gynecology Clinic. This decision follows after the agreement was signed in 2007 between the Ministry of Health and the HIF, which states that the cyto-laboratory at the Gynecology Clinic will not charge for one PAP test per year performed to an insured woman (IN_16_PM_SK_a). This element resembles the period when part of the primary gynecologists were public, and when all PAP tests performed in these facilities were free of charge for the patient. However, while previously not much attention was paid as to the frequency of screening, in the time being the right to make PAP test without co-payment is **once a year**. All insured female persons, regardless of their age, have the right to be screened under the above mentioned terms within the insurance scheme, a fact which was confirmed by all interviewed gynecologists.

However, in practice some private gynecologists, mainly the ones which are not concessionaires and which made completely private investments for their offices, do charge the costs even for the first PAP test in a year (IN_02_PG_KU; I_15_SG_KU_b). This is because they use the cytology services offered by a private laboratory, which is not HIF contractor, considering it as offering better quality for the PAP sample examination. In most of the cases, the gynecologists do not inform the woman why they charge the PAP test, although the woman has the right for a free PAP test annually, and they do not offer the possibility for the sample from the PAP test to be examined in a laboratory which is a HIF contractor

[8] The HIF gives no definition what a positive PAP test means.

(IN_16_PM_SK_b). The price for the basic gynecological check-up and PAP testing in the private facilities varies greatly, from 25 EUR up to 40 EUR.

While the integrated services are covered by the insurance scheme, **the campaign** for cervical cancer screening is covered by a special program funds from the state budget, disbursed through the Ministry of Health. The total budget of the program is ~140.000 EUR, and it covers: costs for estimated 12.800 check-ups with PAP test (~5,5 EUR each); costs for performing cytology analysis (~3,2 EUR each) and costs for the information and education campaign (~24.000 EUR in total) (Official Gazette of the Republic of Macedonia 2007a). The same amount of ~140.000 EUR annually was assigned to the Ministry of Health for this campaign in the years 2005-2009 (Ministry of Finance 2008). In the program it is indicated that the total number of women covered should be 100% for a period of 5 years.

The **immunization program** in general is covered both from the budget of the Ministry of Health's special prevention programs, and the insurance scheme of the Health Insurance Fund. The costs for the HPV vaccination campaign in 2007 were covered by the budget of the Government and the Ministry of Health, and not from the insurance scheme. Approximately 1,5 million EUR were provided for this campaign, which were to cover the costs for the 12.000 doses of the vaccine for 4.500 girls. The costs of the vaccination service were not calculated within the budget of the program (Official Gazette of the Republic of Macedonia 2008). For the HPV routine vaccination of ~10.000 girls at their age of 12 in 2009, the Ministry of Health envisaged ~2,4 MIO EUR (Official Gazette of the Republic of Macedonia 2009).

Promotion strategies

The health promotion activities related to the cervical cancer prevention which this research paid attention to are:

- counseling of clients,
- information and education of the citizens and
- education and training of health professionals.

The main responsibility for the **counseling** activities within the health system in Macedonia lies in the primary health care services. The interviews with the primary gynecologists revealed that the integrated screening activities, which are opportunistic in the time being, entail a component of counseling. However, more emphasis is placed on the counseling after the screening has taken place, including recommendations about the term of the next examination, and especially in case some changes in the PAP test are reported. Prior to exposing the woman to the PAP examination, the physician fills in a standardized questionnaire which entails data on the education / professional background of the patient, the patient history, births, abortions, hormonal therapy, etc.

There are circumstances when secondary and tertiary level gynecologists perform "women's health services", including PAP examinations without a referral, resembling the primary gynecologist check-up. This happens in cases when they perform privately paid "women's health" servicesF9F, and when they perform PAP screening within the framework of the cervical cancer program. However, according to the perceptions of the physicians, as well as their well established roles within the health system, they do not have the responsibility for the general counseling of the patients. Their perceived as well as expected role in the counseling, reported in all interviews with the secondary and tertiary level hospitals, was solely in case of a positive PAP result (I_03_SG_PP_c; I_15_SG_KU_c; I_09_TG_SK_c).

The campaign was also envisaged to entail **"Information and education"** element, designed as a "…media support and awareness rising campaign for prevention of cervical cancer, through TV commercials and information and education printed materials" (Official Gazette of the Republic of Macedonia 2007a). This campaign was also designed to contain an element for promotion of the need for the women to select a primary gynecologist. The task to coordinate the media campaign was assigned to the Institute for protection of mother and child, the Macedonians' women's lobby, and the Parliamentary "Equal opportunities" commission, but other NGO's were included as well, the most involved of which was "Zivotna iskra" (O_01_SK_a; O_02_SK; O_03_SK). Approximately 17% of the budget of this campaign was dedicated to the information and education campaign (Official Gazette of the Republic of Macedonia. 2007a). Although the program was envisaged to cover the uninsured women, the media messages reached the insured women as well. The media campaign was more intense in 2007, and less in 2008. Therefore, it is estimated that in 2008 there were less women which made PAP test as a free service offered through the campaign. The media coverage of the Program was considered as a necessary component, as in the first two years of the Program (2005 and 2006) when such activities were not envisaged, no woman used the opportunity to perform free-of-charge PAP test (O_01_SK; I_12_NGO_SK_a).

Apart of the media campaign, the promotion was accomplished through open access workshops, organized as a mode of direct contact with the women. They were designed as events which offered possibility for education by and discussion with professionals in the field, mainly physicians. They were organized as a joint event with the program for the breast cancer prevention, as a package called "prevention of the cancer of the female reproductive tract" (O_01_SK; O_02_SK; O_03_SK). While in 2007 the workshops were held mainly in the local communities of the cities, in 2008 there was an attempt to cover the rural areas (I_12_NGO_SK_b). Some of the workshops were held in bigger companies, NGO fairs etc. (O_03_SK). The workshops were however not a continuous activity. They took place only during the months October-December. They were visited mainly

[9]As explained in the Resources section of this report.

by women and the participation of the male population was minimal. Printed leaflets were distributed at all workshops. The workshops were visited by both insured and uninsured women, and were identified as an opportunity to get in contact with the uninsured women directly, which would otherwise be very complicated (I_12_NGO_SK_c).

Both the media messages and the education messages at the workshops, visually as well as content wise, were directed only to the women, stressing her responsibility for this segment of her health (HPV Association of Macedonia 2008; O_01_SK; O_02_SK; O_03_SK). The role of the men was completely neglected. Through the interviews with stakeholders involved deeper into the gender issues in health, it was indicated that the behavior change in this segment needs much longer and sustained efforts than the possibilities offered within this campaign (I_12_NGO_SK_d).

The HPV pilot-vaccination project was also very intensely covered on all medias, written and electronic, but also on billboards on the streets, speeches by the prime minister etc. (I_12_NGO_SK; Vlada 2008a). The messages were dedicated to the parents, primarily the mother, and the main message was the cancer protection. Brochures and other printed materials contained all necessary information for the vaccine, including the necessity to continue with the regular PAP screening. They were printed bilingually (Macedonian and Albanian) in order to get bigger outreach. There was a special web page designed and available, and an open help-line; however, this website was discontinued as soon as all available vaccines were spent. The direct contact with the target audience with regards to the vaccination was not a practice, except the opportunity when the parent and the child came for vaccination.

As the vaccination campaign was mainly located in the Institutes for Health Protection (with exceptions of only a few institutions for "women's health services"), the primary gynecologists were not included in its design and conduct. There was a possibility offered that the primary gynecology health care services are involved in the vaccination; however, this possibility was only announced in a few media, and not by direct contact with the target primary health care institutions (I_06_PG_SK). There were complaints by some of them that they did not receive any information or education related to the vaccine directly from the organizers of the campaign (I_05_SG_PP_b). As the HPV vaccine was covered intensely in the mass media, which released both information for and against its use, the public, including the professionals gained contradictory information for its safety and efficacy (IN_04_SG_PP_c; I_15_SG_KU_d; I_12_NGO_SK_e; I_09_TG_SK_d; Vreme 2008).

The **health education** in the childhood and adolescence is regarded as essential in the development of the healthy habits and responsible behavior (I_05_SG_PP_c; I_12_NGO_SK_f). It is included in the curricula of the child's education only in 2007 with the reforms of the health education. "Health promotion" as a subject is included as an elective subject in the 7th, 8th or 9th grade, and the topic of sexually transmitted diseases is covered with the program.

However, the quality of the education process of this subject can not be judged still, as it will begin in few years (Bureau for development of education 2008).

The training regarding the cervical cancer prevention that the health professionals gained, as expressed in the interviews, was mainly during their course of higher education, but also within the framework of the regular professional conferences, symposia, and workshops organized by the professional associations, the physicians or some NGO's (I_03_SG_PP_d; IN_11_TG_SK_b). The continuing medical education for medical personnel is obligatory according to the Law for Health Protection (Official Gazette of the Republic of Macedonia 2004). However, the continuing medical education is not an obligation for the cytotechnitians, which as a result have not received any official training during the course of their everyday work, except the regular supervision by the superiors (IN_14_PAT_SK). No open educational gathering specially designated to the current strategies, aimed at all participants in the process, could be identified as taking place prior or during the course of the campaigns.

Process and performance measures / health information system

The State Institute for Health Protection, as a scientific public health institution, is responsible for the collection and analysis of health status and care-related data, as well as surveillance of communicable and non-communicable diseases. It designs the procedures for the obligatory reporting by the health care providers (SIHP 2009). The research identified that the data gathered and the reports produced by this institution are mainly of quantitative nature and no reports on the qualitative performance of the health care system are readily available to the stakeholders in the system and to the public (IN_08_MC_SK_a).

With regards to the cervical cancer prevention activities, the health care providers submit regular epidemiologic data to the SIHP. However, they are mostly limited to the cancer morbidity and mortality data (I_03_SG_PP). There is a cancer registry existing since 1995, but its content is not readily available on an 'easy to use' media (internet for example). Macedonia is also one of the few countries which cancer register is not a member of the European Network of Cancer Registries (ENCR 2009).

In the time being there is no single and comprehensive citizen health database. The health card is still paper based, although there is a project envisaged for the electronic health card (Ministry of Health 2009). There are separate health records for a single person for the visits to the general practitioner, and separate for the "women's health services", which stay at the offices of the selected GP and/or gynecologist respectively. However, only the check-ups made by the physician in charge are noted in these records. There are no mechanisms to assure that there is a valid and traceable record of all results from the PAP test performed to a single women (I_03_SG_PP_e). The research revealed differences in the records keeping among different primary

gynecologists – some use only paper based and others have their local computer based databases; some give the results of the PAP smear in the hand of the patient, others keep them only in the records at the doctor's office, and some do both (IN_02_PG_KU_b; I_03_SG_PP_f; I_15_SG_KU_e; I_06_PG_SK). The research could not identify existence of any written procedures on how to handle the medical results of the PAP test, nor within the framework of the campaign, neither during the integrated screening activities.

The **database of the PAP smears** is limited only at the level of individual laboratories. The cytology laboratory of the Clinical Center has a database of the women which undergo PAP testing, and whose smears have been analyzed in this laboratory. This laboratory's database is linked to the database of the Institute of Oncology, at the same Clinical Center, so a registration of the smears, including their follow up is facilitated. However, nationally based database of such type does not exist, thus no comprehensive data can be obtained, and the tracking of opportunistic screening is limited. There is an attempt of registration of the taken PAP smear in the health card of the patient; however, as the health card is still only paper based, and the method of registration of the PAP smear is not harmonized by all health care facilities, it does not prove efficient. Within the framework of the campaign, there have been cases identified of a women undergoing PAP testing more times within one year.

There is a general notion, confirmed by more interviews with different stakeholders, that the reports from the programs and activities of the health services are not being circulated and available on disposal of the stakeholders in the process. Therefore, the transparency of the processes is being questioned (I_03_SG_PP_g; IN_16_PM_SK_c; IN_14_PAT_SK_b).

The use of evidence based medicine in Macedonia is left at the discretion of the individual physician. The **clinical guidelines** for practicing evidence based medicine were prepared in 2006, as part of the Health Care Sector Reform Project, credited by the World Bank. They are however prepared basically using foreign models, and in many instances not adapted to the Macedonian circumstances. "They are not yet fully implemented/used in the healthcare system" (Euro-Asian Initiative for Patient Safety, p. 41), as a result of the lack of regulatory framework, but also the culture of the health care providers. (I_15_SG_KU_f; I_09_TG_SK_e). The interviews with the physicians during the research revealed a strong belief that there is no need of written evidence based guidelines. Some of them claimed that "the said word has the same significance as the written one, and there is no need that somebody tells them with an order what to do professionally" (I_03_SG_PP); others stated that the evidence in medicine is learned during studying and specialization; some denied their own responsibility in developing guidelines, and expected that a higher level institution should write them (I_05_SG_PP_d). There were also assumptions that Macedonia does not have enough infrastructure to apply standard treatment guidelines (IN_11_TG_SK_c), or that it is a "political issue" (IN_02_PG_KU_c). The research identified no **quality**

manual existing and implemented in any of the steps in the process of cervical cancer screening and vaccination.

The **performance monitoring** of the health care institutions is being implemented only through a system of inspection, conducted both by the Ministry of Health and the Fund for Health Insurance, as an established control mechanism by the contracting body. The primary gynecologists which have contracts with the HIF are also subject to this inspection system, which is more quantitatively oriented (HIF 2008b). The question is: "is something accomplished?" and not "how has it been accomplished?" (I_06_PG_SK_g; IN_16_PM_SK_d). This system of inspections is regarded as the only quality control which some of the interviewees – gynecologists experienced. However, it is not aimed at the professional medical and clinical auditing of the physicians' treatment decisions (I_16_PM_SK).

Existence of a phone line and a box for complaints from the patients in some of the hospitals, is being regarded as one of the rare **"patient satisfaction"** indicators. No informant during the research pointed out any valid patient satisfaction survey (I_03_SG_PP_h; I_06_PG_SK_h; I_09_TG_SK_f).

There is no **accreditation** system for the healthcare institutions and no merit system exists, nor in the legislative provisions neither in practice. One of the perceived roles of the Clinical center, as the biggest and oldest tertiary level health care facility, is to supervise the other health care institutions, primarily the general secondary level hospitals in the smaller towns (I_03_SG_PP_i). However, this role is not performed systematically, and no commissions for professional supervision could be identified with the research, although there are indications that they existed in the past (I_09_TG_SK_g ; IN_11_TG_SK_d).

None of the methods used in the study identified any quality control of the counseling activities during the screening and the vaccination.

The quality of the taken PAP smear sample is being reported back to the physician by the laboratory on the same form where the results are being reported. However, no official follow-up training has been conducted for the gynecologists which show underperformance in smear taking (IN_14_PAT_SK).

The interviews with the relevant professionals from the two biggest cytopathology and histology laboratories revealed that there is a system of internal quality control of these laboratories, by repeated examination of randomly selected sample. However, the system of external quality control is limited only to verification of the cytopatology with the histology result. No accreditation system exists (IN_13_PAT_SK_b; IN_14_PAT_SK). The research did not identify if this finding is valid for the other, smaller laboratories.

With regards to the "campaign for free PAP screening", the **indicators** for its success are the number of women which used the free PAP service in the designated health centers and in the designated time. However, having in mind that there is no nationally linked database of the cytolaboratories, the baseline

data before the campaign should be taken with care when giving comparisons with the achievements of the campaign.

The HPV vaccination as a project has also been evaluated only by the number of women showing interest and being vaccinated, and by their age (IN_01_EPI_KU_b).

The Law on protection of patients' rights was endorsed recently – in July 2008 (Official Gazette of Republic of Macedonia 2008b), and its provisions are still being efficiently implemented. As an illustration is the fact that the HIF does not have provisions how to deal with patients asking for a second opinion by a different physician other than their primary gynecologist (IN_16_PM_SK_e; HIF 2008b).

Table 4: SUMMARY OF MAIN RESULTS

Analytical cathegory	national context assessment (the policies, guidelines and recommendations) and "theoretical" design of the programs as presented in the official national documents	empirical assessment (the actual implementation of the programs in practice)	the international context - policies and guidelines
Resources			
	- ~300 gynecologists (~15/100.000 total population) - ~50% in primary HC, ~50% in secondary and tertiary HC - primary women's HC - private, but HIF contractors - secondary and tertiary HC - mostly public - system of "selected" gynecologist within the insurance scheme - many women bypass this system and use the private services with "out-of-pocket" payment - secondary and tertiary level "women's health" facilities many times act as primary - big regional difference in the distribution of gynecologists - ~25 cytopathologists and 10-20 cytotechnicians in the whole country - PAP examinations are performed using conventional cytology - colposcopy's becoming a routine in primary services; not all secondary services have a colposcope - 5 public laboratories which perform HPV DNA test - Immunization performed by the Institutes for Health Protection; pediatric services - existence of system of patronage nurses		14,48 gynecologists / 100.000 total population = EU avearage (WHO 2009)
Basic design of prevention programs			
screening interval	- 5 years (as per the published MoH program) - 2 years (HIF policy)	1 year	3-5 years (European Communities 2008a; WHO 2006)

screening and vaccination modality	- opportunistic screening - planning phase of pilot organised screening in one town - pilot vaccination of 4.500 women on a first come-first served basis - nation-wide vaccination for 2009	- opportunistic screening - pilot vaccination of 4.500 women on a first come-first served basis	- organized screening with call/recall system - every country should evaluate the economic impact of HPV vaccination using tailored models reflecting local epidemiological and cost data (ECDC 2008)
integration of the programs / strategies for sustainability	- screening - integrated in the health care services at all levels for the insured women; campaign for the uninsured women - vaccination - still a campaign, announced routine vaccination of girls aged 12	- screening - integrated in the health care services at all levels for the insured women; the campaign goes for 2 years in a raw, but covers both uninsured and insured women - vaccination - still a campaign, announced routine vaccination of girls aged 12	" Wherever vaccination is provided, it is vital that the message that immunisation is an adjunct, not a replacement for cervical screening, is communicated." (ECDC 2008)
target group and age range	- for screening - all women aged 19-65, regardless of their insurance status; the total target population being spread in 5 years (as per the Ministry of Health program) - HIF target is 25% / year of the insured women - for the pilot vaccine - 4.500 girls aged 9-26 - nation-wide vaccination - girls aged 12	- screening for all women, regardless of the age, 6 months to 1 year after sexual debut - pilot vaccination - girls aged 9-26	"Recommendations on the age to initiate HPV screening should aim to maximize detection of early cervical cancer cases while avoiding the bulk of transient HPV infections. It is thus important to carefully define country-specific HPV prevalence graphs as well as the age-specific incidence of cervical cancer; There is minimal benefit and substantial harm in screening below age 25." (IARC 2005)
Financial aspects			

-	- provider payment methods - capitation for primary HC; fee for service for specialist-laboratory services; - the woman has a right for annual free of charge PAP examination at her primary gynecologist, as part of the insurance package; the next PAP examinations in a year is with copayment; - the woman can make free of charge PAP test within the framework of the program at higher level institution; - vaccination for girls 9-26 - free of charge at the side of the user	- provider payment methods - capitation for primary HC; fee for service for specialist-laboratory services; - screening - once a year free of charge in one part of the primary gynecology facilities, except when cyto-examination performed in a private laboratory; - the woman can make free of charge PAP test within the framework of the program at higher level institution; - vaccination for girls 9-26 - free of charge at the side of the user	
Promotion strategies			
methods to increase coverage	- offering possibilities for uninsured women to perform PAP screening - campaigns -media, IE activities - HIF stimulation through defining targets for the primary gynecologists' performance		
patients' counseling	- in general – responsibility of primary gynecologists - the other gynecologists – counseling only in cases of cervical changes	- gynecologists at all levels perform PAP test, but only primary gynecologists take the responsibility for counseling - counseling mostly after the PAP examination - primary gynecologists role in vaccination counseling neglected	"The communication strategy for cervical cancer screening must be underpinned by robust ethical principles and ensure that the information developed is evidence-based, 'women-centred' and delivered effectively, taking into account the needs of disadvantaged

mass information and education /cultural sensitivity of media messages		- strong media coverage - direct contact public gatherings for screening - promotion of the HPV vaccine as an "anti-cancer" vaccine	groups and enabling women to make an informed choice about participation at each step in the screening process." (European Communities 2008a)
education & training - health professionals	continuous medical education - obligatory	- congresses and symposia - no special training for stakeholders involved in the campaigns	
Process and performance measures / health information system			
existence of quality assurance and control systems	- no system of accreditation of hospitals - Law on protection of patient's rights endorsed recently - clinical guidelines prepared in 2006 - no quality manual for the screening or vaccination	- Law on protection of patient's rights still not effectively implemented - the clinical guidelines not used in practice	"The programme design must permit evaluation. An experi-mental design that is suitable for evaluation of new screening policies in organised settings is recommended". (European Communities 2008a)
indicators used	- performance monitoring - only through inspections - indicators are of quantitative nature only - No. of women screened, No. of women referred for colposcopy, No. of accomplished training sessions - example of a patient satisfaction indicator: box for complaints		"Population-based information must be established for continuous monitoring of screening process indicators". (European Communities 2008a)
information and data management	- no central screening database on a national level - paper based health card - cancer registry since 1995 - no written procedure for the storage of the woman's health file		"The information system is an essen-tial tool for managing the screening programme; computing the indica-tors of attendance, compliance, qua-lity and impact; and providing feed-back to involve health professionals, stakeholders and health authorities". (European Communities 2008a)

DISCUSSION

Historical considerations

Historically, in correlation with the health policies in the previous socialist system and the social health insurance scheme, the cervical cancer screening has been included in the basic benefits package for the insured women: free of charge when done at primary gynecologist, and with co-payment when done at tertiary level institution, due to the tendency to promote the use of primary level health care and restrict the unnecessary overload of the tertiary level facilities. This approach of integrating the cervical cancer screening within the "women's health protection" segment of health care has continued and represents the current "mainstream" practice related to this issue.

The available resources and the organization of the health care services at primary, secondary and tertiary level, show that in general there is clear division in the responsibilities of the institutions and health professionals, which most probably is a result of the historical setting of the health system. The cervical cancer early detection activities show consistency with this organizational structure. Most of the gynecology services at all levels, but also the cytology laboratories, which worked under the health insurance scheme were public. This offered a possibility for creation of a planned human resources strategy, which took care of the number of health care personnel in different specialties, necessary for covering the needs of the population. The number of gynecologist per citizen is noted to be in accordance with the other European countries; however, their territorial distribution was shown not to be perfect, partly due to the natural tendency of centralization of the facilities in the capital.

The transition of Macedonia resulted in "insufficient level and poor quality of economic growth", evident in the "poor performance of the labor market since its independence" (The World Bank 2003, p.2). The level of unemployment in Macedonia currently accounts to ~ 35% - official reports, and the estimated level of grey economy is high (State statistical office 2008b; The World Bank 2003). The unemployed people are by Law entitled to health insurance through the social institutions of the system. However, there are certain minimum criteria which a person has to fulfill in order to benefit from this social insurance, as for example – having his/her personal documents settled, re-registering at regular intervals at the employment agency etc. Also, in case the Agency offers a job to the unemployed, and the person refuses to take it, there is a chance that this person is taken out of the registry of unemployed citizens. The other categories of citizens entitled to health insurance (the retired, the farmers, the citizens with social protection etc.) also have to fulfill certain minimum criteria and be registered at the corresponding institutions of the system. The HIF data reveal that 4,2% of the population do not fulfill even these minimal criteria and therefore are not entitled to the health benefits through the social health insurance. There is also certain portion of the insured citizens, which do not have

the contributions regularly paid, probably due to the weak economy and lack of existing functional system for ensuring regularity in insurance fees payments by the employer[10] or the corresponding body. As a result they can not use the health services according to their needs. Speaking about the cervical cancer prevention programs, the Government estimated that the total number of these two categories of women, referred to as "women without regulated health insurance" is 60-65.000. This represents ~10% of the target group, currently defined as "the women aged 19-65".

Under pressure and lobby of the women's organizations at first place, and under the influence of the WHO "Health for All" strategy, emphasizing the importance of cancer control (O_03_SK_a), in 2004 the cervical cancer screening was declared as one of the basic rights of the women in Macedonia as per the Law on Health Protection (Official Gazette of the Republic of Macedonia 2004). This induced the need for design of a program which would be targeted especially to the women without their health insurance regulated (I_12_NGO_SK_g; IN_07_MC_SK_b). Allocating financial resources for this purpose, the Government made a big step forward in showing the willingness for promotion of the "women's health", and showing the determination for non-discrimination on the basis of health insurance, thus protecting the principle of "affordability" in the protection of the rights of the patient (Official Gazette of the Republic of Macedonia 2008b).

Another starting stand-point for the current design of the cervical cancer prevention strategies is the fact that although the PAP screening was historically offered free of charge at primary level gynecologists, there were only estimated 10% of the women, which took this opportunity and had their PAP test done within the one year interval, as per the practical recommendations by the physicians. The screening in Macedonia has never been systematically organized, with certain exceptions of some pilot projects and attempts for introduction of regional organized screening to a defined population group, which were not long-lived (IN_13_PAT_SK_a; I_10_TG_SK_a; IN_11_TG_SK_a). This fact undoubtedly is one of the root causes of the low coverage. Even so, if a comparison is made with the coverage data from other European countries, where no organized screening is still implemented, the conclusion is that the coverage of 10% annually is still very low. In Germany for example, the smears are similarly offered through the health insurance scheme without a call-recall, but the annual uptake is ~50% (Anttila et al. 2004; European Communities 2008b). The reasons behind the low coverage in Macedonia might lie in the traditional view-points of the Macedonian women and families, limited access to the gynecological services, stigma, fear of cancer, non-confidence in the health facilities, lack of information and education, lack of public organized action and promotion (I_12_NGO_SK_h).

[10] This situation is expected to be improved, due to reforms of the salary payment system, launched in January 2009.

The attempt to deal with the two aspects of the problem of the early detection of the cancer of the cervix, resulted in designing a "vertical program" for promotion of cervical cancer screening, as described in the chapter Basic design of the programs.

The choice of screening target group and coverage increase methods – effective strategy or a "window" for opportunistic screening?

Two goals and two target groups could be identified within the framework of the vertical program:

I. Ensuring the right to cervical cancer prevention health services and increasing the coverage among the disadvantaged group of women who do not have their health insurance regulated (referred to as "uninsured women" in the text to follow), which are considered to have high background risk and hard to reach – estimated 10% of the women aged 19-65 [11];

II. Increasing the coverage of the cervical cancer screening, through promotion of the PAP test as an early detection method to the estimated 90% of the women in Macedonia, which do not use their right to perform PAP test as part of their basic benefits package.

The activities envisaged to achieve both of the above goals were:

- offering free of charge PAP testing at a secondary and tertiary level institution;
- mass education and advocacy activities in the form of workshops, as well as promotion through electronic and written media.

The uninsured women could clearly benefit from the offered possibility to be screened free of charge. The resources made available through the vertical program were to cover the needs for 12.000 women annually, i.e. coverage of 20% of the estimated total number of uninsured women. The initial plan was this program to continue for 5 years, within which period 100% coverage would be achieved. These services were officially envisaged (included in the officially documented program design) to be affordable only for the uninsured women, but in practice they were available to all women, regardless of their health insurance status.

The possible ground reasons for the decision to offer this possibility both for insured and uninsured women, which came about during the course of the research, could be:

[11] *This is the age group considered as target group for screening.*

- the willingness of the Government to show that the programs which they design promote the principle of equity among the citizens (Official Gazette of the Republic of Macedonia 2008b).
- the PAP screening was offered free of charge to the insured women as well, as offering a service "free of charge" was seen as the most efficient strategy for its promotion (I_15_SG_KU_g);
- the activities envisaged to increase coverage were not appropriate for the uninsured women, as a particularly hard to reach target group, and this was not foreseen as a possible obstacle to mobilize 12.000 uninsured women;
- the goal to include 20% of the uninsured women was set too high, so the available resources would not be used up if the target group was limited to the uninsured women only.

Another controversial aspect of the design of the vertical program, was the switch of the responsible institutions for the delivery of the screening services in 2007. While in 2005 and 2006 the primary gynecologists were completely involved in the Program, in the years to follow higher level health care facilities took over the responsibilities. As this decision has both financial and ethical implications, the research tried to explore the reasons behind this decision.

One of the possible explanations for not choosing primary gynecology facilities for performing the free-of-charge PAP examinations is their privatization, which took place in 2007, in the same time period when the screening Program was launched. The general financial environment in which the primary gynecologists, especially the concessionaires worked in the beginning of their establishment as private entities was still fragile. As the new HIF contractors, their obligation was to provide health services for the insured women, and they had a right to decline working with the women not covered with the health insurance, in case no common ground was found on the terms these services would be performed. The secondary and tertiary level institutions in contrary were in majority public and as such they were much easier partner for negotiation of the terms and conditions under which to perform the free-of-charge screening. This is the most probable reason for including them in this public health initiative by the Ministry of Health, as the main designer of the Program.

However, the choice of secondary and tertiary gynecologists as the responsible for taking PAP smear, would mean overburdening their capacities at one side, and depriving the patient of the right to be counseled at the other, as the higher level gynecologists do not recognize the counseling of the patient as their responsibility (I_03_SG_PP_j; I_09_TG_SK_h).

The choice of the biggest cytology laboratory, which is based at a tertiary level institution, as a place where all samples of the campaign would be examined, by some was regarded as an opportunity for achieving higher quality of the cytology examinations, as this laboratory is regarded as a reference one (I_09_TG_SK). By others, on contrary, this decision was seen as a possible threat to the quality assurance, as the resources in this laboratory were not adequate for a "campaign-

like activity", i.e. increased number of PAP samples in a short period of time (IN_16_PM_SK_f; IN_14_PAT_SK). The facts that the waiting time for the samples to be examined was much longer than the usual, and that there were cases when the results were not returned to the institution which took the samples, might be taken as confirmation to the later assumption (I_15_SG_KU_h; I_03_SG_PP_k).

One of the most evident outcomes of all activities related to cervical cancer prevention, as designed and implemented by the relevant institutions in 2007 and 2008, was the promotion of the "opportunistic" screening. The insured women were offered a possibility to perform PAP examination at their selected primary gynecologist, but also to use the opportunity to make free of charge PAP test at a secondary/tertiary level facility, within the framework of the campaign. At the same time the cervical cancer screening registration system, identified as having significant shortcomings in terms of its comprehensiveness, did not allow for efficient control of the frequency of screening performed to a particular individual. All this resulted in the women actually using the opportunities offered to them (I_10_TG_SK_b), performing more PAP examinations during the year, and overburdening the system in terms of its human and financial resources. This was confirmed with the data from the main cyto-laboratory in the Gynecology Clinic in Skopje, as presented in Table 4.

Table 4: Report on the number of PAP tests performed – Cyto-laboratory, Gynecology Clinic Skopje

Year	Total PAP smears	First PAP smears	First / total PAP smears
2004	62.744	57.000	~91%
2005	55.851	47.000	~84%
2006	64.326	55.621	~86,5%
2007 - total	72.851	54.699	~75%
2007 - regular	51.170	41.474	~81%
2007 - campaign only	21.681	13.225	~61%*

* The repeated PAP examinations were mainly not due to medical reasons.

Source: IN_14_PAT_SK

Increasing the overall coverage of the cervical cancer screening (i.e. PAP examinations) was one of the identified goals of this program. Although the coverage as an indicator is more suitable for an organized approach to the screening for a disease, for the purpose of assessment of the programs in Macedonia, the coverage was estimated as the number of women performing

PAP examination in a course of one year[12], in relation to the total target population.

The data from the main cytology laboratory at the Gynecology clinic in Skopje, which was the only laboratory where the smears from the campaign were reviewed, lead to an estimation that the coverage at the end of 2007 was not increased. [13] The main ground reason for this is the "opportunistic screening", as mentioned above. For an illustration: 40% of the women which performed PAP examination within the framework of the campaign, have had another PAP test done previously; there were also 221 women which performed PAP test three or more times during the campaign in 2007 (IN_14_PAT_SK). It was noticed that the same women which performed free PAP test within the campaign in 2007, used that opportunity in 2008 as well.

Table 5: Estimation of the PAP screening coverage in Macedonia in 2007.

Year	First PAP smears = women screened in the cyto-laboratory at Gynecology Clinic – exact no.	Other cyto-laboratories – estimation[14] (~10% of total)	Coverage (total population – 610.000)
2004	57.000	~ 6.000	~ 10,3%
2005	47.000	~ 5.000	~ 8,4%
2006	55.621	~ 6.000	~ 10,1%
2007	54.699	~ 4.000	~ 9,5 %
2007 - regular	41.474	~ 4.000[15]	
2007 – campaign only	13.225	0	

[12] The field research identified that the examination was practically recommended at a 1 year interval.

[13] The 2008 data were not yet available at the end of the field research; however as the design of the program in 2007 and 2008 was identical, no major changes were expected in 2008 either.

[14] The shortcoming of this methodology is that due to the lack of national cervical cancer screening registry, the exact nationwide coverage could not be deemed, and these figures are only estimations.

[15] This figure for 2007 would be lower as a % of total compared to the other years, due to the fact that certain % of the women which used the services of the other laboratories regularly, in 2007 took advantage of the free screening offered as part of the campaign, and their samples have been reviewed in the cyto-laboratory at the gynecology clinic.

The situation analysis which was done prior to the onset of the "vertical program" was quantitative, taking in account only estimations of the number of uninsured women, number of PAP tests performed etc. The research did not identify any qualitative analysis performed on the root causes for the situation, nor any KAP study. It was revealed that certain stakeholder groups are involved more profoundly in the design of the programs – as are the tertiary level professionals and health care institutions, and the NGO's. However, the primary and secondary level gynecologists' perceptions are that they were neglected in the process of program design (I_06_PG_SK_i; I_03_SG_PP_l; I_18_PG_SK_a; I_05_SG_PP; I_15_SG_KU).

The experiences with the implementation of the vertical program in relation to the integrated activities in 2007 and 2008, as well as the recognition of the importance of the active participation of the professional community in the programs' design, implementation and evaluation, resulted in a shift of the paradigm, and important changes in the design of the program for 2009, namely:

- significant decrease of the target coverage for uninsured women;
- rollout of a pilot organized screening program with call/recall system, in one town in Macedonia – Prilep;
- design of a national screening database (Official Gazette of the Republic of Macedonia 2009a).[16]

Is "more" better?

The examination interval (**screening frequency**) and the group of women eligible to be screened (defined by the **target age range** among other features) are two of the minimum defined criteria which should be documented in the screening policy, in order the screening activities to be understood as taking place in context of a program, regardless of whether it is organized or not (European Communities 2008b, pp. 14-15).

The clear evidence-based recommendations for an organized approach to the screening, given by more international documents which refer to both developed and developing countries, are that the screening should start in the age range of 20-30, and should be performed at an interval of 3-5 years (The Council of the EU 2003; European Communities 2008a; WHO 2006). The summarized evidence reflected in the EU guidelines clearly shows that in order the desired level of effectiveness and subsequently cost-effectiveness is ensured, the strategy should be to increase the coverage and implement population-based approach, rather than to increase the frequency of screening (European Communities 2008a, pp.

[16] As the program for 2009 is only in its beginning phase, the analysis of its realization in comparison with the provisions set in the document, were beyond the timeframe of this research.

22-24). The WHO shares the same paradigm, supporting the concept of "reducing the number of smears per women per lifetime in favor of more women in the population having fewer smears":

> New programs should start screening women aged 30 years or more, and include younger women only when the highest-risk group has been covered; existing organized programs should not include women less than 25 years of age in their target populations; in the age group 25-49 years, a three-year interval can be considered if resources are available; annual screening is not recommended at any age (WHO 2006, p.11). Countries with medium levels of resources should aim to provide national coverage by cytology screening for cervical cancer at 5-year intervals to women 30–60 years old (WHO 2002, p.67).

Even in a "non-population based" program, there is no clear evidence that more frequent screening, and onset of screening activities at an earlier age is justified. There is no evidence that performing cytology examination to the woman at a 1 year interval provides better protection from cervical cancer than examination at 3 or 5 yearly intervals. The conventional cytology as a method has proven low sensitivity for detection of the disease, "which can be improved by lowering the test threshold for a 'positive' result but only with concomitant loss in specificity, resulting in more false-positive results. When screening a population for a very low-prevalence disease, even a small percentage change in specificity affects a large number of women because the vast majority of women screened do not have the disease" (American Cancer Society 2002). The increased number of false positive results has an effect both on the health system by increasing the possibility for over-diagnosis and subsequently the costs associated with the procedure, but also on the women themselves, by accentuating the possible undesirable outcomes of the screening test, such as psychological consequences to the woman, in a form of anxiety or fear. The natural history of HPV infection further deepens this problem and too frequent examinations may result in over-treatment and inappropriate intervention of cervical lesions, which if untreated would have spontaneously regressed. The same would be true when speaking about decreasing the age range of onset of screening activities.

The upper age limit, although in some guidelines is set to be at the age of 60 or 65, is not specified in the Council Recommendation on Cancer Screening (The Council of the EU 2003). There is a general consensus that the incidence of cervical cancer in older women is almost entirely confined to the unscreened and under-screened (American Cancer Society 2002). This clearly has influence on the local policy recommendations, and influences the ambiguity in the international recommendations.

When speaking about the eligible age and the frequency of screening, the experiences with cancer screening in other developed countries show more pronounced differences within and among countries in the programs for

screening for cervical cancer, than for other cancers (European communities 2008b; Holland 2006).

> Screening interval remains a controversial issue in the United States. While the evidence supports the conclusion that conventional cytology can be safely performed at two- to three-year intervals, many women and providers in the United States may be more comfortable with annual screening. A key factor is the limited sensitivity of the conventional Papanicolaou (Pap) test. A significant proportion of false-negative conventional cytology results are due to inadequate sampling; improvements in the ability to obtain an adequate sample would increase the sensitivity and effectiveness of conventional cytology… Prevailing management paradigms, medicolegal issues, economic factors, and societal expectations are all factors in determining the balance between sensitivity and specificity for a screening program. Risk perception, understanding, and acceptability all vary among individual patients, care providers, and policy makers (American Cancer Society 2002).

In all EU countries which have population-based screening implemented, the screening interval is either 3 or 5 years, and the target age range is 23 / 25 / 30 until 60 / 65, showing the adherence to the recommendations. However, in the countries with non-population based programs the intervals usually vary between 1 and 3 years, and the target age range is in general wider and with more pronounced variations than in the countries with population-based approach. In USA however, the policy decision is to use sexual activity-based screening initiation criterion at age cap at 21, rather than age-based, while the choice of exact age at which to cease screening is arbitrary (American Cancer Society 2002). In some countries the screening intervals are not equal within the recommended target age range, and it depends on the age of the woman and the background risk (eg. France, Hungary, Portugal, USA). In general the frequency of screening episodes decreases as the woman's age and the number of subsequent negative smears increases with time (European communities 2008b; American Cancer Society 2002).

One of the research outcomes with strong evidence was that the general risk perception among the gynecologists in Macedonia is that it is not safe and it is unacceptable for the woman to be screened less frequently than once a year, regardless of the age. One of the explanations for this is that the lack of quality assurance of the elements in the process – basically the smear taking and the cytology examination, is a direct threat to the woman, in case the screening interval is shortened (I_18_PG_SK_b). These attitudes are reflected in the practical recommendations which the gynecologists give to the women, but also in the management paradigms set by the policy makers – the Ministry of Health and the HIF. The research identified no comprehensive and effectively implemented written guidelines, procedures, protocols or recommendations with regards to

the cervical cancer early detection activities. The "vertical program" itself, which was brought with an official regulation published in the Official Gazette, recommends that women 19-65 should be the target of the screening activities, but it does not contain clear provisions on the frequency of screening which is implemented in practice. The only written Standard Treatment Guidelines, which are anyhow shown not to be promoted and implemented among the professionals, do not contain clear recommendation on the frequency and target age for "PAP examination" as well. The ambiguity in determination of the clear recommendations is evident in the HIF policy as well: the basic benefits package in Macedonia entails annual PAP examinations free of charge, regardless of the age of the woman; the objectives / targets set to the gynecologists are designed to provide incentive to performing PAP at a two yearly interval; and the number of examinations with ~10% co-payment is not limited. Having in mind that the co-payment amounts to only ~1 EUR per performed PAP test, and the rest of the cost is still covered by the insurance (the HIF), the efficacy of this strategy of the HIF in safeguarding the capacities (financial and human) remains questionable.

The challenges of the millennial invention

The HPV vaccine, which was launched on the world market in 2006, as a mean of primary prevention against a cancer related agent, is marked as a breakthrough invention and a novel experience which links immunization, cancer control and sexual and reproductive health. However, having the HPV vaccine in hand, the professional community stands in front of a big challenge.

The period in which the vaccine has been followed-up in clinical studies so far is 5-6 years, "which is a relatively short period of time, when it is known that it takes approximately 20 years on average from exposure to an oncogenic HPV type to possible development of cervical cancer" (National Board of Health, Danish Centre for Health Technology Assessment 2007). This prevents the scientific community to claim its real-life effectiveness against cervical cancer as an end point, but also questions the possible need for booster vaccination, the interaction with other vaccines etc. (ECDC 2008). These would be some of the epidemiological data necessary for optimizing the vaccination schedule and subsequently the design of the vaccination program.

Nevertheless, the existing evidence for the efficacy and safety of the vaccine, undoubtedly provide strong basis for subsequent evaluation of its impact to the health of the citizens. Making it available and affordable to the citizens results in protection against serious and fatal disease. However, the fact that this is a vaccine against an infection which is sexually transmitted, with clinical implications primarily for the women, creates an open table for discussion of the cultural implications of its promotion and implementation, especially in the more conservative societies. To explain the justification of vaccinating 12 year old girls against an STI, is a challenge on its own. The belief that the vaccination may change the sexual behavior and lead to an unwarranted feeling of security is not

to be underestimated. Also, its use in girls only questions the fairness of the strategy. Although vaccinating men is still not proven as economically justified, the infection might affect the male population as well (National Board of Health, Danish Centre for Health Technology Assessment 2007).

The financial aspects of the HPV vaccine are maybe the strongest argument for the necessity of careful and participatory decision making. Although expected its price to be subject to negotiations, this vaccine is by far more expensive than the most expensive vaccine in the vaccination schedules (ECDC 2008). The financial burden would be even higher, having in mind that this technology does not replace the cervical cancer screening as a proven effective method for cervical cancer prevention, but contributes marginally in increasing the effectiveness against cervical cancer. The 'catch-up vaccination' is a strategy which "includes at the start of the routine vaccination program some birth cohorts older than the target age who would have been vaccinated routinely had the vaccination program started several years earlier" (ECDC 2008). This strategy significantly increases the cost of the program during the first years. The herd immunity, the cross protection, the reduction in the other HPV related diseases and the significant costs of the treatment of cervical cancer, are the parameters which on the other hand, all have favorable effect towards the cost-effectiveness profile of the vaccine.

The currently available cost-effectiveness studies, most of which are company-funded, show substantial differences in the models used and reveal very different cost-effectiveness profiles of the vaccine, ranging from $2.964 / QALY gained to $33.700 / QALY gained, depending on the elements used in the modeling (ECDC 2008). The ECDC concluded that

> …the economic analyses performed to date seem to indicate that adolescent female vaccination strategies when combined with cytological screening have a cost-effectiveness ratio similar or even lower (especially when dynamic models accounting for herd immunity are used) than that of other preventive or therapeutic interventions commonly applied…; it must be stressed that, due to the many differences between countries with regard to cost of screening, therapeutic measures and the wide variability of medical services, every country should evaluate the economic impact of HPV vaccination using tailored models reflecting local epidemiological and cost data (ECDC 2008).

A survey performed by King et al. (2008) within the Vaccine European New Integrated Collaboration Effort (VENICE) project, revealed that 15 out of 28 EU and EEA countries have made a recommendation, all favoring vaccine introduction, while in 10 out of them an official decision for introduction of the HPV vaccine in

the national immunization schedule has subsequently been takenF17F. The countries that decided to introduce HPV vaccination adopted varying vaccination policies. The different approaches are particularly evident in terms of target ages, decision of whether to implement parallel catch-up campaigns or not, but also on the level of reimbursement by the state mechanisms. There is an observed association between the level of the national GDP and the decision to introduce the vaccine in the country: the four countries which were among the first to introduce the vaccine – France, Germany, UK and Italy, are the top four ranked European countries in terms of national GDP (King et al. 2008).

> It is also worth noting that among the five northern European countries none actually took the decision to introduce the HPV vaccination (as of January 2008) despite the fact that these countries generally have a well-developed public health infrastructure and also potentially have the resources needed to fund a routine HPV vaccination. Four of these countries (Sweden, Finland, Iceland and Norway) reported a target population coverage rate for the national cervical cancer screening program above 75%, which raises a question about the possible impact of a successful screening program on the decision not to introduce HPV vaccination (King et al. 2008).

At least one ad hoc study was undertaken by 14 (50%) of the surveyed countries to support the decision-making process for HPV vaccine introduction. These included: disease burden studies, mathematical modeling studies and/or economical assessments. Mathematical modeling projects to support the decision-making process for HPV vaccination introduction were reported as complete or ongoing by four of the five countries that have decided to introduce the vaccine at first place during 2007 (King et al. 2008).

Having decided to include the HPV vaccine in the national immunization schedule of the girls at their age of 12 in Macedonia (Official Gazette of the Republic of Macedonia 2009) and the full reimbursement through the immunization program of the Ministry of Health, reinforces the strong commitment of the Government to tackle this problem as a public health issue and to offer equal access opportunities to the health services. This "rights-based" approach is particularly important having in mind that higher risk of cervical cancer exists among women of lower socioeconomic status (IARC 2005, p.6), which otherwise would not be able to afford such an expensive technology. Performing the vaccination in a systematic way also avoids the 'opportunistic' vaccination, which might not target the groups most at need and might limit the public health effect of vaccination (ECDC 2008). Marked as a country with low coverage of the cervical cancer screening, Macedonia is expected to have significant short-term incremental benefit of the vaccination in terms of

[17] Data as of 31.January 2008.

preventing the HPV infection. The decision to introduce the HPV vaccine in more or less the same time with the cervical cancer screening campaign also represents excellent opportunity to integrate these two prevention methods in terms of health promotion and education strategies.

However, having in mind the economic aspects of the strategy for HPV vaccination as described in this research, one could not avoid the question whether this approach is not too expensive for a country with an income level of Macedonia. Only the purchase of the doses of the vaccine necessary for the population vaccination program, is expected to cost 2,4 million EUR, which, as a comparison, accounts to almost 2% of the total budget of drugs and medical consumables. Additional financial burden was the design of the pilot vaccination phase, which happened before the official decision for introduction of the routine vaccination took place. Although regarded by some as a "catch-up" campaign (I_10_TG_SK), the design of this 'pilot vaccination' does not really resemble the design of the catch-up campaigns in the other European countries. The pilot vaccination in Macedonia initially indeed aimed to offer equal opportunities to the girls of the older age groups and included the girls aged 9-26, as per the examples in some other countries. However, the best practices show that the "catch-up" campaigns are initiated in parallel timelines with the routine vaccination and take place in a course of few years (NHS 2009; King et al. 2008); however in Macedonia it took place in a short period of time of only 2 weeks, and was performed on a "first-come-first-served" basis, due to the low envisaged coverage (the resources were envisaged to cover 4.500 girls, which represent ~ 2% of the target population). This fact directly compromised the goal to offer equal opportunities for this vaccine to all girls. Therefore, the more appropriate term for this program would be "pilot vaccination" or "HPV vaccination promotion campaign", aimed at investigating the expected response level among the population, as stated by high level politicians as well (M_A1_Vacc_27.11.'08).

The research could not identify any economic evaluation performed as part of the planning stage of the process, which could have contributed significantly to justification of the decisions for implementing of the vaccination and its specific delivery strategies. This can be taken as an example of the lack of scientific approach to the priority setting in health in Macedonia.

Although seemingly much less important than the previously discussed points related to the HPV vaccination, the counseling of the girls and women plays an important role in sustaining the "rights-based" approach of the strategy. Paying particular attention to informing and motivating women to attend the screening programs, even if they have been vaccinated, would be crucial in alleviating the possible, very serious side effect of the vaccination in terms of offering the vaccinated girls a false sense of security, resulting in lower attendance at screenings, and reduced effectiveness of the existing screening program. Keeping the continuous attention to the importance of the control of risk factors is of great significance as well.

The research revealed that the role of the primary gynecologists in the counseling of the female population with regards to the vaccination is neglected. This might mean loosing one of the opportunities for an effective counseling. Being the pillar of the "women's health" services, and the first line promoters of the sexual and reproductive health, the primary gynecologists could play substantial role in advising the women on the vaccination of their daughters, motivating females to attend the screening programs even if they have been vaccinated, thus promoting the sensitizing role of these women in their community.

Evaluability assessment

The process of evaluation and performance management of programs and activities is an imperative not only for the screening in an organised setting. A well-functioning evaluation system must be integrated into any policy/program cycle, starting from the planning phase, to the delivery of outputs and results. "The contribution of program evaluation is potentially greatest in innovative policy areas where achieving success cannot be taken for granted and where implementation is not always straightforward" (European Communities 1995-2008).

Numerous methods and techniques for evaluation are practiced, depending on the type of intervention, the purpose of the evaluation, the stages of the programmes/policies and the policies and programs realities. The pre-defined indicators produce quantified information relevant to the monitoring and evaluation of a program, which in most cases need to be interpreted by means of comparisons.

> Increasing numbers of systems of indicators are created for the purposes of "performance management". These systems are a form of New Public Management that emphasizes results and impacts obtained, as opposed to older forms of management based on the allocation of resources and the control of outputs (European Communities 1995-2008).

The quantitative evaluation is useful as it is identified to allow aggregate judgments and trend analysis to be made, and it "provides an overview which informs follow-up, qualitative analysis". However "in order to be useful in evaluation work, indicators need to be used in conjunction with qualitative findings. To interpret indicators, it is necessary to consider the context as a whole, the factors which help to facilitate or hinder the performance of the program, the rationales of the program, and the process of implementation" (European Communities 1995-2008).

With regards to the **integrated cervical cancer screening** activities in Macedonia, which are based on the activities of the gynecologists, the only

system for performance measurement is set by the HIF, within the framework of the contracts monitoring and inspection. The system of determining "objectives" or targets to be reached by the primary gynecologists, shows the willingness of the HIF for establishing benchmarks for basic performance parameters. In this system – the cervical cancer early detection activities, represented through the level of PAP smears taken by the gynecologist, the performed colposcopies and the performed "education workshops on the topic of STI's", are given particular attention, by dedicating most of the extra capitation points and extra income to the gynecologists. This should represent not only a financial incentive, but also an awareness rising factor. However, through the interviews with the gynecologists certain potential threats to this system are identified. They consider the level of the capitation point in general as low, which poses a question whether the financial incentive is really an incentive. Another threat is that the upper level of the financial stimulation is set to performed PAP tests to 25% of the women in a year. Although this is more than twice the average number of PAP tests currently being performed in the country, it is still far below the desired coverage. This system does not contain provisions in case of higher activity by the gynecologist. Since the PAP test is not obligatory, this could have a counter effect on the number of performed PAP tests, due to the tendency for cost-containment, which is one of the adverse incentives of the capitation as a provider payment method (I_06_PG_SK_f).

The measurement of the performance of the gynecologists conducted by the contracting body, related to cervical cancer early detection activities, is largely about accountability, emphasizing the financial and monetary measures, thus using only one technique, which is quantitative in its basis. The above mentioned scenarios were shown as an illustration of the possible obstacles to the effectiveness of the evaluation processes, in case only one sided – quantitative measurements are taken into account. The systematic follow-up of the quality control system of the samples taking, the quality control of the process of the counselling or follow-up of the patients, are other examples where qualitative descriptions or qualitative interpretations of the findings could not be identified, but would be much appreciated in case an effective evaluation system is to be established.

The designs of both programs (campaigns) for cervical cancer screening and vaccination, as indicated in the officially published documents do not contain clear provisions on the methodology for their evaluation. The identified indicators are mostly connected to the number of women which within the framework of the programs undergo PAP screening or show interest for the HPV vaccination. This once again shows the tendency of limiting the performance monitoring to only quantitative measures and interpretations.

The shortcomings in the **quality assurance system and performance evaluation**, have a particular significance in the effective provision of the counselling activities both for the screening and the vaccination. The neglected role of the primary gynecologists in the HPV vaccination, also the fact that

screening is performed not only by the primary, but also by higher level gynecologists, which do not have the inherited and recognised role in the counselling of the patients, are elements which represent significant potential threats to ensuring the right of the woman to be counselled. This might have serious implications for their health, but also for the effectiveness of the two campaigns / programs implemented side by side. Having no system for measuring the performance and the quality of the counselling process and leaving this element of the patient care to the sole responsibility of the physician, just speaks about the lack of recognition of this threat.

An important factor for the success of an evaluation process is its participatory nature.

> Incorporating the voice of these intended beneficiaries - local communities, marginalized groups and new economic entities - in evaluations implies more than asking their opinions. It also implies incorporating their criteria and judgments into an evaluation and accepting that their experience and benefits are the justification for program interventions. This is consistent with the logic of bottom-up, participative and decentralized approaches that are common now in socio-economic development (European Communities 1995-2008).

The tendency for incorporating the beneficiaries in the decision making and implementation of the programs and processes related to cervical cancer in Macedonia is evident. However, considering the participatory, bottom-up approach in the design of the monitoring and evaluation strategies of the programs and processes as well, would be an essential strategy in case a sound and transparent judgement of their success and effectiveness is to be placed. The research also identified lack of procedures and culture of reporting of the performance and results of the programs to all stakeholders. This could have a negative influence on the tendency for establishing a culture of trust and accountability, primarily between the decision makers and designers of the programs at one side, and the medical community at the other.

Accreditation is one process in a range of different approaches for **checking and standardizing the quality of health care** delivered by health service organizations (Scrivens 1996). The experiences from other countries speak that it is considered as a rather complicated system; therefore many of them use other methods and approaches for controlling quality (Scrivens 2002). Most of the quality review systems use written statements or standards that describe the expected good practice for the organizational processes and procedures, against which the organization is assessed (Scrivens 2002).

The health care in Macedonia is not subject to accreditation; however, no other systematic methods and approaches for assessing quality were identified in the course of the research, neither in legislation, nor in practice. This might be the root-cause for the lack of awareness for the need of written standards, procedures

and protocols in the day-to-day activities of the hospitals and the health professionals in general – consequently in the activities related to cervical cancer prevention. The non-existence of culture of measuring quality in health might also be one of the explanations for the reluctance by the professional community, primarily the physicians, to use the external evidence synthesized in the tools such as "evidence-based guidelines" in an integrated manner with the own individual clinical or other expertise and the patient's choice, as a mean to increase the quality of the health care decision making (Sackett et al.1996).

The process of monitoring and evaluation in general, inevitably raises the question of the **data sources and evidence** that it should be based on, as well as the existence of basic rules and guidelines for their processing. The Macedonian "Law for evidence in health" is endorsed very recently (February 2009) so its provisions could still not be effectively implemented (Official Gazette of Republic of Macedonia 2009b). The non-existence of legal framework to some extent explains the lack of awareness for the need of data quality management manuals, protocols for data monitoring and usage etc. The lack of a comprehensive nation-wide screening database is a serious threat to the effective evaluation of the screening activities, as it prevents the managers and the evaluators of the programs to precisely estimate the baseline and mid-term data prior and during the interventions. Consequently, no sound comparison and benchmarking could be performed, which in this case is necessary for placing judgements on the program effectiveness and success.

CONCLUSION

Having recognized that the incidence of cervical cancer, which is among the highest in Europe, and the cervical cancer early detection coverage, which amounts to only 10%, justify investment in programs that will deal with this health problem, the Government of Macedonia decided to act in three levels:

- strengthening the existing, integrated early detection activities ,
- designing and implementing vertical "campaign–like" special Program for cervical cancer screening ,
- promotion of the possibility for primary prevention, through making the HPV vaccine available to the citizens.

The commitment of the Government is evident in the decision to make substantial level of financial and human resources available for the design and running of different activities at these three levels. Offering possibility for non-insured women to perform PAP examination within the framework of the special Program for cervical cancer prevention, as well as including the HPV vaccination in the national immunization schedule, thus making it available as a free-of-charge vaccine for all girls, stresses the determination of the Government for the rights-based approach towards the promotion of the "women's health", following the principles of affordability and non discrimination on the basis of health-insurance status.

However, in order this commitment results with achievement of the desired health outcomes, the dedicated resources would have to be allocated for effective planning, implementing and monitoring of the activities. Although the **international guidelines** show relatively harmonized approach in dealing with this problem, the truth is that there is wide variety of policies and programs even among countries with similar level of resources. The WHO clearly states that effective cervical cancer prevention programs can be implemented in both developed and developing countries if the basic guidelines are followed (2002). According to the evidence synthesized in the recommendations given by relevant international bodies, "the screening should be organized and population-based, aiming for attainment of wide coverage and ensuring that adequate systems are in place to appropriately manage screen-positive women" (ACCP 2004). Effective quality assurance should follow the screening process, in order the public health benefits and cost efficiency are achieved. With regards to the HPV vaccination, the ECDC recommends that "every country should evaluate the economic impact of HPV vaccination using tailored models reflecting local epidemiological and cost data, due to the many differences between countries with regard to cost of screening, therapeutic measures and the wide variability of medical services" (2008). Particular attention should be paid to the fact that the vaccine is effective against only a portion of the causative agent; thus the needs of integration of the prevention strategies – the vaccination with the screening, and the strategies for

education, awareness rising and behaviour change for prevention of the infection and risk factors are evident (ECDC 2008).

While the integrated cervical cancer early detection activities in Macedonia follow the traditional model of primary-secondary-tertiary level health care, with defined roles and responsibilities of the stakeholders, the creation of the vertical program for screening, as well as the HPV vaccination program are new developments in the field. The tendency for inclusion of the stakeholders, especially the civil sector, in the design and implementation of the programs and processes related to cervical cancer in the country is evident and should be strongly supported. However, having revealed that other groups of stakeholders, as for example the primary and secondary gynecologists, are to an extent marginalised in the processes related to these new developments, rethinking of the **participatory approach** should be considered, the possible obstacles identified and removed, especially having in mind that although vertical in their design, these programs use the existing human and technical health care resources. This is particularly important having in mind that two complex and demanding population-based programs – organized screening and HPV vaccination, are being announced to commence in 2009.

The effective dealing with a problem which involves young adolescents, but in the same time is related to the sexual and reproductive health of the women and which outcome might be fatal, demands gaining insight in the views, standpoints and the culture of the direct **beneficiaries**, especially the women. Performing baseline surveys could help in revealing cultural and socio-economic specificities of the different target groups (for example the reasons for the low screening coverage, the attitudes towards a vaccine against an STI, etc.), which in turn could help in dimensioning, focusing and rationalising the envisaged activities. This sort of research could also help in identification and understanding of the obstacles, as well as the hidden opportunities, useful for improving the current and design of future programs.

In order for Macedonia, as a country with much lower income level than most of the other EU countries, to be able to justify the investment and prioritising the **HPV vaccination**, as a novel but expensive technology, the decision makers and the scientific and professional community need to perform a sound economic assessment, tailored to the circumstances in the country: the epidemiologic status of the population, the relevant local economic and market developments, the parallel cervical cancer screening program and its effectiveness etc. However, to determine the most suitable approach for the delivery of the vaccine to the citizens, the cultural perceptions of the beneficiaries, as well as the post-marketing assessments of the vaccine itself, should also be carefully considered.

The elements which are given attention to in all screening evidence based guidelines are: defining of the target population and frequency of screening; effective recruitment strategies to achieve high coverage (promotion, counseling, training, financial aspects); the capacities of the health care system both for prevention, as well as follow-up – diagnosis and treatment; health information

and quality assurance system. The Macedonian programs and policies related to cervical cancer screening, but also the vaccination, are identified as being ambiguous in defining even the **basic guiding elements and principles**. This subsequently leads to disharmonies during the implementation phase.

The issue of the **target age range and the recommended frequency of screening remains** controversial and non-defined in Macedonia, despite the ongoing efforts to place the activities related to cervical cancer prevention in a programmatic framework. However, the clear definition of these parameters will require special attention within the framework of the policy, not only because it is a minimum requirement for the screening activity to be understood as taking place in the context of a program, but also because it contributes substantially to the effective allocation of human and financial resources. This necessity will be even more evident now, with the recent trend of initiating and planning an organized population-based approach to the screening in Macedonia. While making this decision, not only the risk perceptions and societal expectations should be taken into account, but also the existing national and international medical and economic evidence, as well as the available human, financial and technical resources.

The **promotion** segment of the screening and the vaccination receives particular attention. It happens in a form of mass education: media promotion and public workshops. The inclusion of the health education in the curricula of the child in its primary education should be taken as a great future opportunity to tackle the problem of the women's health in general. However, the counseling of the clients – the women and their partners, as a mode of "personalized" and confidential communication, targeting both women and men, receives little attention. This in part results from the neglected role of the primary gynecologists in the implementation of the special vertical screening and vaccination programs in the previous couple of years, but also from the general lack of quality control methods of the counseling services. Diminishing the importance of the counseling as a mode of sustainable health promotion, means loosing invaluable opportunities for the health system as well as the clients themselves, but also posing direct threat to the health of the women. Informing and motivating women to attend the screening programs, even if they have been vaccinated, would be crucial to alleviate the possible side effect of the vaccination in terms of offering the vaccinated girls a false sense of security, resulting in lower attendance at screenings.

The **health information system** in the country was identified as being of questionable quality, especially in terms of its nation-wide comprehensiveness, partly due to the absence of national legislation related to the evidence in the health care. However, as the legal framework is already in place as of February 2009, its effective implementation would mean providing sound basis for better design and management of the health programs in general, but also for precise determination of outputs, outcomes and impact, necessary for placing judgements for their success. The tendency towards the complex interventions of

the population-based screening and vaccination, discloses the imminent need for development of focused, efficient and integrated information system, prior to onset of any specific action.

The research revealed suboptimal performance of the **quality assurance** of the processes related to cervical cancer prevention in the country, both the integrated activities, as well as the special screening and vaccination programs. The measures of performance of the gynecologists, imposed by the Health Insurance Fund, are mainly of quantitative nature, aimed at assuring accountability towards the third party payer. The evaluation methods of the special programs, similarly measure the crude attendance to the screening and vaccination within the framework of the campaigns. However useful in providing aggregate judgements and basis for comparisons and benchmarking, the quantitative techniques are "weak in explanation of the bottom-up understandings and the expectations of the grass-root actors, the interactions of the different contextual factors, the impacts of the intervention for the different groups of beneficiaries, the judgements of the stakeholders". The effective application of a combination of different evaluation and quality assurance methods and techniques, which should preferably be planned in a participatory manner, would be expected to foster transparent and objective judgement of the quality of the health care services, processes and programs, reveal the unexpected opportunities and threats and bring to light the answers not only to the question "What works?", but "How it works?" and "Why it works?" (European Communities 1995-2008).

The overall design of the screening program as was performed in 2007 and 2008, where the basic PAP test, as the essence of the early detection process was performed in higher level health care institutions in parallel manner with the integrated PAP examinations performed in the primary health care, contributed substantially to the promotion of the **opportunistic screening**. This contradicts the guidelines given by the international community. The lack of comprehensive screening database, coupled with the suboptimal performance of the quality assurance system, contributed significantly to this phenomenon. As there are indications for a shift of the organization of the screening program in Macedonia towards **population-based model** as of 2009, which according to the guidelines "must permit evaluation" and "must ensure and demonstrate good quality at all levels" (European Communities 2008a), special attention will have to be placed to developing and strengthening the evaluations capacities at all levels: the planning and the design, but also the delivery of outputs and results. Proper assessment of the resources available for these population-based activities, paying special attention to the human resources for cytology practice, as well as the territorial distribution of the primary gynecologists, could help in dimensioning the activities and avoiding the phenomenon of diminished quality for the sake of obtaining higher quantity of services.

All recommendations given as a result of this research, aim to contribute to the more effective allocation of the resources dedicated to the segment of the

"women's health protection" dealing with cervical cancer prevention, promotion of the scientific element in the decision making processes in health, ensuring the participative nature of the policies and programs, and strengthening the current trend of the "rights-based" approach towards the health problems in the country.

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ANNEX 1

EXPLANATION OF THE CODES

The CODE of the documents names consists of the following elements:

Type of record _ Record No. / Media source _ Subtype of record _ Place / Date

Type of record:

I – interview

O – observation

M – media account

IN – interview notes

FN – field notes

Subtype of record (if applicable):

PG – interview with primary gynecologist

SG – interview with secondary gynecologist

TG – interview with tertiary gynecologist

MC – interview with specialist from "mother and child care" departments

PM – interview with policy / program maker at central level

NGO – interview with NGO activist

EPT – interview with epidemiologist

PAT – interview with pathologist

Vacc. – vaccination related media account

PAP – PAP test related media account

HPV – HPV related media account

Place

SK – Skopje

KU – Kumanovo

PP – Prilep

ANNEX 2

CITATIONS – FIELD RESEARCH

(sources - the interviews, the observations and the media accounts)

(I_06_PG_SK_a): "Well, the association of private gynecologists of RM has 110 members which have contracts with the Fund and secondary gynecologists are from "Mala Bogorodica" and "Remedika"… and other private gynecologists, 20-30 more in Macedonia, which do not have contracts with the Fund".

(I_03_SG_PP_a): "…me, I can not be a selected gynecologist, but I deal with all patients that will come to me, because we don't ask for a referral from anybody. He comes without referral, finishes his business and it's over. For now – it is like this. I think in future it'll be that he can go only at the selected doctor, and then our task will be limited to curing, and the prevention will not be our task."

(IN_04_SG_PP_a): "For a general gynecological check-up in the hospital, we do not ask for a referral from the primary selected gynecologist. We ask for a referral only in case there is a need to open a patient history and the women to stay in the hospital for more days."

(I_05_SG_PP_a): "Unfortunately we are only a few colleagues at the department up here and in couple of years, as we get old, we'll be retired, and this department will have to be locked"

(I_06_PG_SK_b): "Yes, we send the samples at the gynecology clinic, although there are other cytological laboratories now. Look, this is a sample from cytological laboratory "Citolab" – diagnostic laboratory, which has a contract with the Fund, uses the same filling form, same results form, and of course – has a cadre from the Clinic."

(IN_14_PAT_SK_a): "In the other towns in Macedonia in the general hospitals, there are histopatologists: in Tetovo, Gostivar, Veles, Ohrid, Bitola, Strumica, Prilep and two in the Military hospital. They perform triage and definitive diagnostics."

(IN_04_SG_PP_b): "The biopsy and PAP samples – we read them here in this hospital. We have two pathologists employed, and the results are ready in one week."

(I_09_TG_SK_a): "…the liquid cytology, yes we had it for only two years, and then the reagents were missing."

(I_06_PG_SK_c): "Well, it was introduced here, and was functioning for a year this, so called liquid PAP, which is taken in a medium. The Clinic performed it, and we even went for an education. They had two laboratories for preparation of such smears; so, we take the sample here, in a medium, the medium is taken in one of the laboratories and after handling it there, it is taken to be read in the cyto-

laboratory in the Clinic. …it worked for about a year, and then, I don't know the reasons, but it did not continue. And I think it is more precise…"

(I_06_PG_SK_d): "the State offered help to buy colposcopes. It gave us 100.000 denars each to buy colposcopes. Of course, these are not enough money to buy it, but an average colposcope can be purchased for 150.000 denars…."

(I_03_SG_PP_b): "Here in Prilep we do not perform colposcopy. Unfortunately we don't have colposcope here. Well, maybe now in the following months we'll get one."

(I_15_SG_KU_a): "No, colposcope is also primary health care. We had one, Zeiss, but it stayed at the concessionaires…So, we do not have a colposcope."

(IN_07_MC_SK_a): "In the framework of the Program for health protection of mother and children, earlier there was an element for reproductive health, and it envisaged that the patronage nurses, while performing the family visits, open a women's record, and they were to make interviews with the female about her awareness with regards to the control of her health, including questions for PAP screening and mammography. But these data stayed in the record of the woman, and they were not analyzed at a national level. Unfortunately, this initiative died."

(IN_02_PG_KU_a): "Well, the target age for the PAP is from 16 up to 100 years. It could be even 13, 14, it is of 'no damage', and the only criteria is that she is sexually active."

(I_09_TG_SK_b): "PAP test once in three years? Well, it could be practiced but only in women older than 65, if the risk factors are less. I accept this. But, as our women are so hard to be mobilized, so it is our luck if the woman comes every year. So, three years is too risky."

(I_10_TG_SK_a): "Ideally all women, in the target age which should be defined, let's say 25-55 - there is no justification for anything else, should be divided in 5 or 3 years. In some countries it is 5, in others 3 years, depending on the resources. And in 3 years let's say, each one of these women should be invited with a letter… And recommendations for age range? It is one thing when we speak about a recommendation when to make PAP test, and another thing when the state is paying for an ORGANIZED screening. Check ups are recommended – if we have conventional PAP test – once in two years or in one year, starting from 18 – 65, one year after the sexual debut. But this is recommendation, this is not screening."

(IN_01_EPI_KU_a): "Yes, it is free of charge for all girls 9-26. We register the vaccinated girls with their names, date of birth, the date when the first dose is applied, and the date when the next doses are due. We do not ask for the health card of the girl."

(M_A1_Vacc_27.11.'08): "During the campaign, the vaccines were used up much faster than we expected. This means that the citizens realized that it is good, and

they went to be vaccinated faster…10.000 girls more than the planned asked to be vaccinated."

(I_06_PG_SK_f): "The objective goes like this: I should make PAP test to 25% of my patients annually. Now, let's say if I have 3.000 patients, I am obligated to the Fund, to take 750 first PAP test in a year, so I can fulfill the objectives and get the capitation points. So, until this day I have 975, and until New Year I will have around 1000. Who will pay me these 250 extra?"

(IN_16_PM_SK_a): "Within the program, there is a Memorandum of agreement between the Ministry of Health and the HIF for not charging anything by the laboratory at the Gynecology-Obstetrics Cinic to the gynecologists."

(I_15_SG_KU_b): "In Kumanovo in average they take 300 denars for a sample."

(IN_16_PM_SK_b): "…some private primary gynecologists send the PAP sample at the laboratory in Sistina for example. Sistina does not have a contract with HIF for this service, so it can not cover these costs. So, these private gynecologists in fact do charge this part of the service, and not the check-up itself, which according to the contract with the HIF is free of charge. Still, this gynecologist should inform the insured women in advance, that in such case she should pay the fee for it."

(I_03_SG_PP_c): "There is no counseling. We take the PAP smear and make gynecologyc check up. There is no counseling. No time for counseling. The counseling is not even foreseen. We can counsel the patient only when the result is back, when we get it, especially if there is some indication, anything, and then we start with the counseling what should be done next."

(I_15_SG_KU_c): "No, we don't council the women and it is not our responsibility. And another thing: I should take 20 samples, and I take 50 in 2 hours. I don't have time enough even to take them, and much less for conversations. We will talk and council when the results arrive. Let's not speak by heart."

(I_09_TG_SK_c): "So we, as a tertiary institution are directly involved in the cervical cancer prevention. I think that in this phase it is not appropriate this way, because it has to be a responsibility of the primary health care, and all positive samples or some unclear things to be selected and referred to us. Well now, the campaign which was going on in this period, maybe was done in order the primary doctors to be relieved, and we resembled primary gynecologists, so we made PAP and screening of patients."

(O_01_SK_a): "A parliamentary representative:…this campaign has certain pre-history. Even in the previous mandate, the women parliamentarians, at the initiative of the NGO's "Zivotna iskra" (Life's sparkle) and the "Association of women in Sveti Nikole", we started a process of change and amending of the Law on health protection. In the current mandate this change was enforced, and free gynecological check-up of all women, once per year was enabled, regardless of whether they are insured or they are not ensured."

(I_12_NGO_SK_a): "Let me tell you one interesting fact: the check-ups without a campaign are worthless, because women are not informed. For ex. –this program started on 1st of January. Until the media campaign started, there was no woman which called for free-of-charge check up…After we started the educational workshops – now there is not enough time to cover all the interested."

(I_12_NGO_SK_b): "This year the workshops were indeed not announced at the TV, because there were no funds for media promotion of the campaign. Last year the Ministry gave additional money for this. But this year the workshops were held in the villages mainly, and it is very easy to promote there. You tell to few leaders in the village and soon everybody knows…There were 50 villages covered this year. Last year there were 70 workshops both in towns and villages."

(I_12_NGO_SK_c): "The uninsured women – we try to reach them on the field. It's just that if you tell them it's only for uninsured – they are afraid that some social privilege might be revoked…because they don't really understand. And when you organize for all women, then they come and understand that it is not especially for themselves. If we make it only for uninsured, one should go and ask them, and people usually don't give such information. You know, usually the uninsured people have problems with their personal documents. Because if they don't have such problems, if they applied in time in the Employment agency, if they are low social class cases, then they get the insurance cards from the authorities. To be uninsured means: you either did not apply on time in the Agency, or you don't have documents, or you have some problem."

(I_12_NGO_SK_d): "The men… we had few men at some workshops. There is a mentality that they consider it pure women's thing. The men are not very interested, until it comes as a problem of their close persons, but they don't want to go to hear it in public. Especially this is true for marginalized and rural groups. There are still stereotypes in Macedonia that this is a women's thing. And to tackle this problem, much longer and sustained engagement is needed."

(I_05_SG_PP_b): "There is no very good approach among the people. I don't know how many have been vaccinated, we don't have any information until now. I only know that the Institute for Health Protection had 100 vaccines. But, that is only an Institute, which performs the vaccination, but the results of that vaccine – who should see it? – Are we the ones?"

(IN_04_SG_PP_c): "How many countries are such experimental animals like ours? There is no need of such a vaccine, its efficacy is not proven".

(I_15_SG_KU_d): "It turned out as if we are a trial region for that Merck vaccine, still not researched. So, some of them started, see. But they say there are some deaths – 3 deaths in America… I wouldn't give it to my daughter, let me be honest. As I spoke with other Professor – he says: Don't touch it! This is because the types of viruses which are present here and in America are not the same."

(I_12_NGO_SK_e): "During the workshops there were lots of questions about the vaccine. There is lots of suspense and lack of knowledge among the common

people regarding the HPV vaccine. Most common questions were if it is useful, if something bad can happen – you know now in the papers there were claims that somebody somewhere in the world died. So, for the safety. There were questions how is this HPV vaccine applied. Some people don't know that it is a classical vaccine. They think it is applied gynecologically. Then about the age etc."

(I_09_TG_SK_d): "I think that the vaccine is good, it is from a renowned company, and it has not shown any side effects. Nowadays, you can find everything on internet. But it should be relevant, lot's of attention has to be paid. There can be a coincidence with any intervention in the medicine. It is like you say – don't buy a car of this type, as it always leads to car crash."

(I_05_SG_PP_c): "Our health education is on a very low level. But it should begin in the schools; kindergardens, schools, faculty, and after all that – the media…And the basic unit is the family, the home…But not "sexual education" – immediately the bad, negative side is stressed, not what's positive… One person as an individual, me or you…we'll go, make lectures and leave…you don't know who understood anything and who didn't. We can not sell the science to the citizen, but we should approach and explain. That's the basics."

(I_12_NGO_SK_f): "There is no sexual education in the schools – I'm certain about that one. About the health education – it is within the framework of the biology class, and I think not much. If we have Religion teaching, it would be good to have sexual education, because many things could be prevented that way. And when we dedicated some time to such things, we could dedicate some more to health or sexual education. I am astonished how can people in the 21st century have knowledge gaps so wide."

(I_03_SG_PP_d): "There's plenty of lectures at different workshops: from the women's NGO's, at some holidays, on TV. There have been, and there still are. That's a permanent thing, this mass education let's name it."

(IN_11_TG_SK_b): "We organized earlier in the gynecological association special trainings for smear taking. The same could be organized now."

(IN_08_MC_SK_a): "Even when we submit the reports, all of them are quantitative, and refer to the number of check-ups. There are no qualitative data or indicators. This implies for the health institutions in Macedonia in general. No quality control system is implemented yet."

(I_03_SG_PP_e): "These records should stay at their primary gynecologist, not at our office. And the results of the samples, the regular ones which are paid by the woman, stay in our records. And these which are free of charge, as it is a mass of paper, we give them to the patient, so she can keep it as a document. So, wherever she goes, she can have it in hands. And these others, which we are accountable for the document, since it was taken at our department, we give them to make copies of, and the original stays with us."

(IN_02_PG_KU_b): "The woman can come only for a consultation for the results. She can not have the PAP result. It stays here."

(I_03_SG_PP_f): "The results of the 'paid' tests stay at our hospital's records. But those which are free of charge, as they were a big mass of samples, we had no place where to keep them, and we simply gave them in the hands of the patients, so she keeps it as a document. And whenever she goes, she should have it in hand."

(I_15_SG_KU_e): "The result is written in a book. We don't give them –they just have a look and we keep them at our records, in each doctor's file. Even these primary gynecologists don't give them, he can only give a copy, and they stay in the records at the doctor's office. And that is better, because the woman will loose it and the primary gynecologist would not be able to have an insight on what has happened, you know. And it is no problem if the woman has a copy."

(I_03_SG_PP_g): "They did not give us any report. They collect the report. In fact we give them report. We only have the results from the samples back."

(IN_16_PM_SK_c): "The Fund have not received any report from the Programs of this or last year."

(IN_14_PAT_SK_b): "We haven't received any other report from the campaign. We give the report actually."

(I_15_SG_KU_f): "They gave us some CD-s 3 years ago with these protocols from the Clinic, but they are not officially adopted from our association. They are not officially adopted, so he can say 'Why did you operate CIN1, by law you shouldn't have!'. There's no such thing, because somebody likes unclear things. But the essence of our work is there – what we do is mainly 90% like in the protocols. Well now, some things – laser vaporization which we don't do, so instead of conization he does LETZ. In this hospital that is not done. But the laser has other problems… and I prefer the classical way."

(I_09_TG_SK_e): "The protocols are written, but not published as a book. They are in some phase, but this phase lasts quite long. They are compiled, revised twice until the time came for printing, and it's been a year since it is finished, but not yet published. There's also a CD with these, also on internet."

(I_05_SG_PP_d): "Are there any guidelines or procedures valid for the whole country? – Of course, we studied them and we know it. That's why we implement it. And about the protocols, if you refer to the protocols, they should be done by a reputable institution, and that is the Clinic. We from the periphery, can not develop protocols, because we are not accredited. – And have you received any protocols from there? – No. What we learned, this is what we know. It stays permanent and you should know how to implement it. I haven't seen anything new in my long working career."

(IN_11_TG_SK_c): "It should be left at the doctor's discretion to individually assess in what interval will he recommend PAP, depending on the personal and family history, socio-economic status, place of living, age etc. In countries like England, France etc., where the infrastructure and conditions for health care are good – the guidelines and protocols can function there."

(IN_02_PG_KU_c): "-Have you encountered any written guidelines for this? –I don't deal with politics. I am a practitioner. –So how you decide on the procedures to do? – By my own lifetime working experience."

(I_06_PG_SK_g): "There's no quality control in our country. We have quantity control. An inspection comes from the Fund and says: 'Please doctor, you have a goal to take 750 PAP. Let's check in your notebooks, take out 5 patient's records – this one, this one and this one, are the PAP tests really taken? Now doctor, you have obligation to perform microbiology examination to every pregnant woman 12^{th}-14^{th} week. Let's see in your notebooks. Do you have receipts that you took these samples? … The colposcopy doctor, you declared that you have 11 positive PAP samples. There is a need for colposcopy to every one of them. There is a form about it, see."

(IN_16_PM_SK_d): "During the inspections, we check in the documentation if the PAP test was accomplished, and we check it – if there is a receipt of the sample by the cyto-laboratory, we don't check if the results are back… and for the lectures for STI's, the doctor should have a letter of confirmation by the director of the school or the faculty."

(I_03_SG_PP_h): "We don't make any patient satisfaction questionnaires. If the patient is satisfied, you will see him again, and if not – he doesn't come back. We don't have any evidence of such type. We keep only medical evidence – the disease history etc."

(I_06_PG_SK_h): "As much as I know, the biggest survey that the Ministry is doing for the satisfaction from the services of the medical personnel, is the open phone line. So, only if you have some negative remarks. Nobody makes a survey for the positive things. This is one way of assessment of the quality. If there are no complaints, then the doctor is good. But what if there are compliments? Why isn't it recorded?"

(I_09_TG_SK_f): "I haven't heard of any survey for patient's satisfaction of the work of the gynecologists. Questionnaire – no; I just know that in any institution, in our clinic too, there is a box for complaints. But that's not it. There is a phone line in the Ministry, but no questionnaire. You can find it in the private hospitals – there is an owner there, so he might be interested."

(I_03_SG_PP_i): "We can't receive any guideline from the Ministry of Health. This is pure professional thing. Our association does not do it either. It was a practice on a national level, assigned by the Clinic, although in these last years it is not present. We communicate with the Clinic less and less in the recent period. Earlier, the Clinic was 'a father', it took care for all of us, we asked for a counsel, and the best practices for the whole country originated there. The standpoints of the Clinic are standpoints for the whole of Macedonia."

(I_09_TG_SK_g): "The Clinic generally does supervision of all medical centers, institutions and gynecologists in the country for the control of the professional activities...But there is no quality control system. I think that the Fund establishes

some commissions, to inspect how the services are accomplished, if they perform good quality work. But something else – no. The hospitals expect from us, they will call and ask for a counsel, or they send a referral. So they ensure that what is being expected from them is done. But supervision of the results – if it is true CIN 1 or something else – there is none."

(IN_11_TG_SK_d): "There is no quality control in the health system. Earlier, there were Commissions for professional supervision, composed of professional people from different profiles, which controlled how the health services are performed. But it stopped in 1994."

(IN_13_PAT_SK_b): "The laboratory does not have a system for external quality control. There is only one way for internal control – we take some samples – randomly, for the second time, and all doctors examine them. Another method is that after an intervention, the cytological and histological findings are compared with the finding before the intervention. We perform internal quality control, by taking random samples. But we have no principle of external control and accreditation. Our laboratory also has a record for the quality of the taken samples."

(IN_01_EPI_KU_b): "Yes, we send them reports how many have been vaccinated, and by age. We do not take any other data."

(IN_16_PM_SK_e): "The right to a second opinion is not taken into account and is not defined."

(O_03_SK_a): "A tertiary gynecologist:…According to the WHO recommendations and its "European regional strategy for reproductive health", which our country has signed as well, and within the framework of this strategy, we are obliged to enforce its provisions… improve quality of the early detection process, providing adequate training of the human resources, promote the measures for protection of sexually transmitted diseases, and perform constant systematic monitoring. In accordance with these recommendations, the Clinic, in cooperation with the Ministry of Health, in the previous 3 months, started to enforce this program, to perform 12.000 free PAP tests."

(I_12_NGO_SK_g): "We were initiators for free of charge check ups for the women, by placing this question in the Parliament through the Equal opportunities commission. The Commission supported it, there were many public hearings, an amendment was prepared which was adopted in the Parliament. According to this amendment, the Government designed a program which it financed this campaign and these free-of-charge check ups with. So, the Government responded to the legal framework given by the Parliament. So, we made this initiative, developed it in the Parliament, found a way to get a support from the women parliamentarians, also from the men, and eventually according to this Law the Government developed the Program."

(IN_07_MC_SK_b): "In 2004 an amendment of the Law on health protection was brought, with which the measures and activities for prevention of the female

reproductive organs' diseases became a guaranteed right of the woman. The Government brought a Program for early detection and prevention of the diseases of the female reproductive organs. This implied for the first time in Macedonia, a vertical program for reproductive health."

(IN_13_PAT_SK_a): "First attempt for an organized screening was made by Prof. Stavrik, in coordination with the Ginekologija Cair in the '70ies".

(I_10_TG_SK_a): "So, the beginnings of the organized screening, but the one which was localized, are in the '70ies in Skopje, and it was a local screening of a defined target group i.e. population…After this, at the end of the '70, meaning '77, '79, I don't know exactly which year, in Gevgelija Prof. Kiril Demirdziev also performed an organized screening with local character."

(IN_11_TG_SK_a): "Earlier, in Gevgelija, there was pretty high incidence of cervical cancer in comparison with the country's average, maybe because it is a town near the country's border, and the risk factors were more present. And it was interesting that Prof. Demirdziev, a "village doctor", with his enthusiasm and influence in the local communities, managed to realize a typical organized screening, with calls and recalls, and in 3-4 years significantly decreased the number of cases with cervical cancer. And that happened in the times when computers were not available."

(I_12_NGO_SK_h): "-So you think lack of emancipation is the reason for the low coverage of the PAP testing? –No, no. I think that the problem lies in how much we animate this issue. I think there is no person which is not interested for the health. It's just the fear, knowledge gap, the discomfort. …The society is what should give support and builds the system…"

(I_15_SG_KU_g): "The women want to make it here. When people hear that it is free of charge, whatever it is – no mistake – they take it – it is free-of-charge. Even if someone does not have a need of it, she comes."

(I_03_SG_PP_j): "The job of taking PAP smear in the hospital is not appropriate. The smear is for prevention, let's make it clear. What have I got to do with it?"

(I_09_TG_SK_h): "-Is there enough time for the counseling and education during the check up? –No, there is not enough time and it is not envisaged so. Sit, take sample, go, the other one is taking off her clothes and that's it. No EHO, no additional check up, no talk, nothing. And when she comes for the result, then – in case something is discovered, I mean if something is positive, then we pay a bit more attention."

(IN_16_PM_SK_f): "At the meetings it was stressed that there is a need for more trained cytoscreeners, because in the moment there is a scarcity."

(I_15_SG_KU_h): "One part of the samples was back in 10 days, but the rest – they are still not here. Maybe because of the holidays. But some things are mixed up – from other towns samples are sent here… Well, they probably have 10.000 samples from all towns. Who knows how they are distributed and what kind of

crowd was it. See, now from other towns are sent in our hospital, and maybe our samples are at other places. Now, a transcript of the results will be needed."

(I_03_SG_PP_k): "We still don't have any results back by now… Last year they were back, but some 150-200 results never came back, they vanished, and some of the results were sent to other towns."

(I_10_TG_SK_b): "Every woman has to be invited with a letter, meaning that it shouldn't be like 'Hey, here there is free-of-charge, come – gather these 5 women which work in the Fiori store, and come here to make PAP – it's free-of-charge.' That way only the opportunistic screening is worsened, unfortunately."

(I_06_PG_SK_i): "They don't listen to people like us: practitioners, who deal with these problems in everyday work, and who would help them make it functional – these things that they don't make functional."

(I_03_SG_PP_l): "They did not ask us for an opinion. They probably arranged everything with the Clinic itself. The provincial hospitals, as we are, are never consulted. We just peform tasks."

(I_18_PG_SK_a): "The campaign – at one side they took the job from us: the patients don't come to us for an examination, they go in the Gynecology Clinic, so a tertiary level gynecologist takes PAP test. We were not included because "they don't want to play with us. We are citizens from 'lower class'."

(I_18_PG_SK_b): "In the other parts of the world, let's say the English Royal College for example, the gynecology recommendations say – PAP examination once in 3 years. But there they examine the samples with very sophisticated devices, and the factor of human mistake is minimal. The whole glass of the sample is placed on the device, and the microscope makes the triage and only the suspected changes are given to the cytologist to read. Here in Macedonia, unfortunately, the cytology service is in some transitional phase… And there are no more than 2-3 cytologysts which work with good quality."

X. E. P. A.

асоцијација за здравствена едукација и истражување

A Member Association of