

Pursuant to the Article 16, paragraph 2 of the Law on Health Care ("Official Gazette of RS", No. 107/05, 72/09 – Law, 88/10, 99.10, 57/11, 119/12 and 45/13 – Law) and Article 42, paragraph 1 of the Law on Government ("Official Gazette of RS", No. 55/05, 71/05 – correction, 101/07, 65/08, 16/11, 68/12 - US and 72/12),

The Government issues

REGULATION  
ON THE NATIONAL PROGRAM FOR EARLY DETECTION OF CERVICAL CANCER

Article 1

This Regulation determines the National program for early detection of cervical cancer and implementation of health care which includes activities to improve health, reduce mortality from cervical cancer and improve the life quality of women.

Article 2

Activities to promote and preserve health are conducted by the National Program referred to in Article 1 of this Regulation which contains defined goals, activities and expected results.

The national program referred to in Article 1 of this Regulation is attached hereto as its integral part.

Article 3

On the date of entry into force of this Regulation, the Regulation on the national program for prevention of cervical cancer ("Official Gazette of RS", No. 15/09) ceases to be valid.

Article 4

This Regulation shall enter into force on the eighth day of its publication in the "Official Gazette of the Republic of Serbia".

05 No.: 110-6916/2013  
In Belgrade, 16 August 2013

THE GOVERNMENT

PRIME MINISTER

Ivica Dačić

# NATIONAL PROGRAM FOR EARLY DETECTION OF CERVICAL CANCER

## 1. INTRODUCTION

Cervical cancer is a global problem, especially in the developing countries. Cytological screening every three to five years can prevent four of five cases of cervical cancer. Still, in order to achieve this success, qualitative organized population screening is necessary.

Considering the significance of this problem and the fact that in the Republic of Serbia each day, in average, cervical cancer takes two women, the Ministry of Health with the professional groups, according to the recommendations of World Health Organization (WHO), analysing the screening programs of other countries and using the experience of the pilot programs in Branicevo district, created the program of organized screening for cervical cancer in our country. This program is adopted by the Government, and is published in the "Official Gazette of RS", No. 54/08 as the National program for early detection of cervical cancer.

Improvement of the National Program for early detection of cervical cancer was done in 2012 and 2013, supported by the European Union and the project "Support to the implementation of the National Program to Fight Cancer in Serbia", the expert team of associates and working groups at the Ministry of Health.

The national program for early detection of cervical cancer is in line with the recommendations of the World Health Organization, aimed to reduce morbidity and mortality from this cancer localisation.

The incidence of morbidity and mortality from cervical cancer is largely dependent on the success of the implementation of prevention programs.

Organized screening program for cervical cancer, along with health education in schools, public promotion of healthy lifestyles, social mobilization of the population, through the good organization of screening, quality control in screening and appropriate data collection and processing, makes a significant contribution to overall reproductive health of women and brings big savings to the healthcare system.

## 2. SITUATION OVERVIEW

### 2.1. Epidemiology of cervical cancer in the Republic of Serbia

Cervical cancer is the third by incidence in the world and with more than half a million new cases each year, makes almost 9% of all cancer cases in women.

Majority of new cases of cervical cancer (about 80%) is found in undeveloped regions, in later stages of the disease when the prognosis is very bad.

The greatest number of death outcomes is evidenced in less developed regions where the mortality rates are approximately three times higher.

With over 1300 newly diseased and approximately 500 deaths, cervical cancer is the second leading cause of morbidity and the fourth cause of mortality from cervical cancer in women. Women in the Republic of Serbia, in 2002, had the highest incidence of cervical cancer (27.3/100,000) in Europe. The incidence of cervical cancer is dropping. In 2008, the rate was 20.9/100,000 which can be explained with the outcome of opportunistic screening. Values of the incidence rates of cervical

cancer in the Republic of Serbia are still among the highest and are approximately twice as high as the average incidence rates in Europe.

With a share of about 6%, cervical cancer is the fourth leading cause of death among malignant tumors in women in the Republic of Serbia. The age distribution of cervical cancer showed earlier a typical increase after 30 years, with a peak incidence in women of 45 to 49 and of 70 to 74 years of age. In recent years, peak morbidity from cervical cancer shifts toward younger ages.

Large regional differences in the incidence and mortality of cervical cancer are recorded in the Republic of Serbia.

The stage of the disease is a major prognostic factor in patients with cervical cancer. When the disease is detected at an early stage surgical treatment is often enough. In advanced disease, it is necessary to apply postoperative or radical radiotherapy, often combined with chemotherapy, which extends the treatment, leading to various complications and significantly increases the cost of treatment.

## 2.2. Cervical cancer prevention

### 2.2.1. Possible causes of cervical cancer

Infection with human papilloma virus (hereinafter referred to as HPV) is the most important risk factor for cervical cancer. Portions of this virus were found in 99.7% of cases of cervical cancer.

HPV virus is so widespread that the majority of adults (70%) once in their lives had HPV infection. Primary infection with HPV does not usually cause any symptoms and most people spontaneously eliminate the virus without being aware of it. In some cases, HPV infection can be maintained without any symptoms for several years.

However, in order that HPV infection leads to cervical cancer, it must persist which requires other risk factors, the most important being: smoking, long-term use of oral contraceptives, immunosuppression (HIV infection, conditions after organ transplants), lifestyle (bad socio-economic conditions) and genetic factors.

Infection with high-risk types of HPV – group of high oncogenic risk (HPV types 16, 18, 31, 33, 35, 45, 51, 52, 56), carries a higher risk of premalignant lesions and cancer. The most common present types of high risk are HPV type 16 and type 18 (cause 76% of invasive cancers).

### 2.2.2. Forms of cervical cancer prevention

The natural flow of HPV infection and the biological behavior of premalignant lesions of the cervix allow the prevention of cervical cancer to be achieved at the primary, secondary and tertiary levels.

Primary prevention includes measures to prevent HPV infection (health education, vaccination).

Secondary prevention involves screening (early detection of asymptomatic forms of the disease).

Tertiary prevention is the treatment of premalignant lesions, thus preventing their progression to invasive cervical cancer.

## 2.3. The implementation of the National program for early detection of cervical cancer

National program of early detection of cervical cancer (hereinafter referred to as screening) is implemented by organizing screening tests in ostensibly healthy population which does not show the signs of disease. The aim of screening is to reduce the incidence and mortality of the disease for which screening is organized. The screening can be organized or opportunistic.

Opportunistic screening represents the unsystematic application of screening tests as part of regular inspection. This includes women who themselves ask for examination or refer to a medical doctor for other reasons. This type of screening has been conducted in the Republic of Serbia for many years.

Organized screening is organized, mass calling the target population for screening mammograms and interpretation of images, accompanied by quality control and reporting. Organized screening is done in cycles over several years (three, five or ten years).

Screening allows not only the detection of cervical cancer at an early stage, but also the precancerous changes, whose removing prevents the development of malignant changes. In countries, mostly developed, in which the organized screening programs are successfully applied for several decades, there has been a dramatic decline in mortality from cervical cancer, eg. the Republic of Finland by 80%.

The screening test is applied in the process of screening for early detection of disease. It should be highly sensitive, specific, easily applicable, simple, painless and relatively inexpensive. The cytological cervical smear (Pap test, hereinafter referred to as the PAP test) meets all these criteria and is one of the best tests for screening in medicine.

The target population in screening for cervical cancer may be different depending on many factors: epidemiological, demographic, human, organizational and financial. European guides recommend that screening should begin between 20 and 30 years of age and last until 60-65 years.

A successful screening should have:

- 1) A large population coverage (coverage should aim for at least 75% of the target population of women);
- 2) HPV triage test (if possible), proper care and monitoring of women with a positive result PAP test, data collection through information systems and quality control.

Opportunistic screening has been performed in the Republic of Serbia, which showed the following shortcomings:

- 1) women's lack of information about the efficiency of cervical cancer prevention;
- 2) low coverage of the target population of women through regular PAP examinations;
- 3) lack of quality control, training and work quality control – interpretation of PAP smears;
- 4) inadequate data collection and reporting, thus no real results;
- 5) insufficient involvement of local governments in the activities to promote the health of women.

### 3. OBJECTIVES OF THE NATIONAL PROGRAM

#### 3.1. General objective

Reduction of women's mortality and incidence of cervical cancer in the Republic of Serbia.

#### 3.2. Specific objectives

- 1) Raising awareness of women about the importance of regular examinations and early detection of cervical cancer, and informing about the importance of screening;
- 2) strengthening the capacity of health institutions for the implementation of screening in terms of ensuring a sufficient number of trained personnel and equipment;
- 3) establishing a system of data collection and management during screening implementation;
- 4) establishment of quality control services in the implementation of screening;
- 5) involving local authorities and civil society in the implementation of screening.

### 4. LEGISLATURE AND SCREENING PARTICIPANTS

#### 4.1. The legal framework

The basis for the implementation of organized screening are the following regulations:

- Health Protection Act ("Official Gazette of RS", No. 107/05, 72/09 - dr. Law, 88/10, 57/11, 119/12 and 45/13 - dr. Law);
- Health Insurance Act ("Official Gazette of RS", No. 107/05, 109/05, 57/11, 110/12 and 119/12);
- Regulation on the national program of health care for women, children and youth ("Official Gazette of RS", No. 28/09);
- Regulations on the nomenclature of health services at primary health care level ("Official Gazette of RS", No. 24/09 and 59/12);
- Public Health Strategy of the Republic of Serbia ("Official Gazette of RS", No. 22/09)
- Decision on the plan of development of health care in the Republic of Serbia ("Official Gazette of RS", No. 88/10);
- Decision on establishing standards for accreditation of health facilities ("Official Gazette of RS", No. 28/11).

##### 4.1.1. Social care for the health of the population in the Republic of Serbia

Within the early detection of the disease, according to the Health Protection Act (hereinafter the Act), shall be targeted at preventative care or screening, according to the respective republic programs. Implementation of screening, according to Article

11, paragraph 15 of the Act, falls within the social care for the health of the population in the Republic of Serbia, and in accordance with Article 45, paragraph 1 of the Law on Health Insurance health care is insured in full force at the expense of the budget of the Republic of Serbia as well as for persons covered by screening according to the respective republic programs.

#### 4.1.2. Activities of the selected physician in the screening implementation

The health care system and the organization of health services are regulated by the Act, according to which the medical activity is performed at the primary, secondary and tertiary levels (Art. 79, 88, 89, 90 and 91). In the process of health care implementation at the health center physician the elected physician conducts all activities defined by the Act (Art. 95, 98 and 99), including work on the identification and elimination of risk factors for the disease and implementing screening programs in accordance with special programs issued pursuant to the Act.

Screening as an activity is mentioned in the Strategy of Public Health of the Republic of Serbia while the screening provisions are discussed in the Regulation on the national program of health care in women, children and youth, as a way of achieving the objective – preserving and improving the health of women in reproductive age.

#### 4.1.3. Screening records

With the aim to collect, keep, process and use data on personality, it is necessary to lawfully regulate legal base for the creation of a new database for screening implementation.

#### 4.1.4. Protection at work

Protection at work in the field of screening is regulated with various regulations. The ISO 15189:2008 quality standard of Medical laboratories is applied for the protection at work – special requirements for quality and competence.

Protection of carcinogenic substances and biological materials is achieved pursuant the Law on Safety and Health at Work ("Official Gazette of RS", No. 101/05), Regulations on preventive measures for safe and healthy work when exposed to biological hazards ("Official Gazette of RS "No. 96/10), Regulations on preventive measures for safe and healthy work at the workplace (" Official Gazette of RS ", No. 21/09) and Regulations on preventive measures for safe and healthy work when exposed to carcinogens or mutagens (" Official Gazette of RS ", No. 96/11).

### 4.2. Participants in the screening implementation

Cervical cancer screening is carried out on the territory of the Republic of Serbia in the form of organized decentralized program.

#### 4.2.1. Republic Expert Board for the implementation of programs for early detection of malignant diseases

Republic Expert Board for the implementation of programs for early detection of malignant disease (hereinafter referred to as the REB), formed by the Minister of

Health for expert supervision over the implementation of organized screening, which through the defined annual plan, performs the following actions:

- 1) provides guidelines for screening programs and performs expert verification of screening programs, considers and adopts models and changes in screening programs;
- 2) provides guidelines for the organization, coordination, monitoring and evaluation of screening programs;
- 3) determines the list of indicators in the process of implementing screening;
- 4) determines and approves the plans in implementing screening and adopts the report on the plan execution and submits them for approval to the Ministry of Health, as well as the models in the implementation of screening programs and their changes;
- 5) conducts the activities in accordance with the plan of activities;
- 6) establishes the draft criteria, standards and norms pertaining to screening programs;
- 7) provides technical support to the Office for the Prevention of malignant diseases;
- 8) Evaluates the screening training program;
- 9) establishes programs of promotional activities related to screening programs, as well as plans for research in the field of screening programs;
- 10) makes proposals for the engagement of individuals or groups of experts to address certain issues in the field of screening and conducts other activities pursuant to the Act and the Minister of Health;
- 11) REB submits reports on its work to the Ministry of Health on a quarterly, semi-annual and annual basis.

#### 4.2.2. The Institute of Public Health of Serbia "Dr Milan Jovanovic Batut"

The Institute of Public Health of Serbia "Dr Milan Jovanovic Batut" provides the necessary expert and logistical (technical) support to the Office for the Prevention of malignant diseases.

The information system of the Institute of Public Health of Serbia "Dr Milan Jovanovic Batut" represents the IT support in implementing screening programs, or collects data from the institutes of public health, forms continually updates appropriate electronic databases. Updated database is available to the Office for the Prevention of malignant diseases.

#### 4.2.3. The Office for the Prevention of malignant diseases

The Office for the Prevention of malignant disease was established at the Institute of Public Health of Serbia "Dr Milan Jovanovic Batut".

The Office for the Prevention of malignant disease is responsible for the implementation of organized screening and performs the following actions:

- 1) coordinates, organizes, monitors and evaluates the implementation of organized screening and provides technical support to other participants in its implementation;
- 2) coordinates training in the areas of screening, in accordance with the plan for the implementation of screening;
- 3) prepares the draft plan for the implementation of screening;

- 4) performs activities of the five-year and annual plans in implementing screening of its competence (education coordination in the field of screening, organizing promotional activities);
- 5) submits the proposal of five-year and annual plans in implementing screening, including a financial plan, to the Ministry of Health and REB, and submits periodic and annual reports on the implementation plan to the Ministry of Health;
- 6) suggests REB changes, additions and new screening programs and models for their implementation to REB;
- 7) prepares and proposes REB draft of criteria, standards, norms and indicators related to the implementation of screening;
- 8) prepares and proposes REB suggestions of guidelines and regulations for screening;
- 9) prepares and proposes REB single form for collecting data on screening (population, test results, etc.);
- 10) issues instructions for preparing reports of the institutes of public health and health centers on the implementation of screening;
- 11) plans and conducts research in the field of screening;
- 12) prepares proposals for the program of promotional activities related to screening;
- 13) submits reports on the screening implementation to the Ministry of Health screening at least once a month;
- 14) performs other activities in the field of screening, with the consent of the REB.

#### 4.2.4. The institutes of public health

The institutes of public health coordinate the implementation of screening in the territory they are established for and perform the following activities:

- 1) appoint screening coordinator and his deputy;
- 2) daily communication and cooperation with representatives of health centers are provided through a designated coordinator and his deputy;
- 3) coordinate and organize health centers and local self-government (representatives of population groups) in order to educate, motivate and increase the response of the local population to screening;
- 4) appoint their representatives in the team for the coordination of screening at the level of health center;
- 5) provide assistance to health centers in the preparation of action plans for the implementation of screening and approve the action plans;
- 6) collect and update data from health facilities which conduct screening (health centers, hospitals) according to a unique pattern, process this data and transmit them in the form reports to the Office for the prevention of malignant disease at least once a month;
- 7) prepare an annual report on the implementation of organized screening and submit it to the Office for the prevention of malignant diseases.

#### 4.2.5. Health center

Health center is the carrier of screening in the territory it is established for.

Health center forms a team to coordinate the implementation of screening, whose member and representative of the institutes of public health it is. Among the team members for coordination of screening implementation persons responsible for screening are appointed.

Health center provides information to screening participants, motivates women invited for screening, receives participants' calls and records the time of arrival to screening.

Health Center performs the following activities:

- 1) every year in collaboration with the institute or the National Institute of Public Health it issues an action plan for the implementation of screening;
- 2) organizes and conducts calling target population;
- 3) keeps call records which should contain (by date and shift) the number of: invited women, managed contacts, the women who refused to participate in screening, examined women, those who were not found at the given address and after repeated calls;
- 4) implements organized screening in separate time and/or place from providing health care to other patients;
- 5) the team for coordination and implementation of screening has a database and submits pattern reports to the competent institute or the public health department.

#### 4.2.6. Cytological laboratory

Cytological laboratory is the accredited laboratory for coloring, interpretation and supervision of cervical smears (PAP smears) on the territory it is created for. It works as a part of primary, secondary or tertiary health institution, or individually.

A cytological laboratory performs the following activities:

- 1) accepts smears (tiles) from health centers and stores after analysis for five years;
- 2) keeps paper and/or electronic documentation necessary for recording its screening tasks;
- 3) processes (colors) smears and prepares them for interpretation (laboratory);
- 4) interprets preparations in terms of categorisation into negative and positive (accredited permanently employed cytoscreeners, specialist in gynecology, biologists, medical technicians, laboratory technicians trained for cervical cytology);
- 5) examines in detail all positive preparations and 10% negative ones (random sample as a measure of quality control); this activity is performed by accredited supervisors – a cytopathologist, a pathologist, a gynecology specialist and a biologist.

A supervisor reports to the selected physician, medical doctor specialized in gynecology at the health center on the results of smear analysis with a unique standardized report within three weeks from the date of tile admission.

#### 4.2.7. Medical institutions of secondary and tertiary health care

Medical institutions of secondary and tertiary health care appoint a coordinator and a nurse who are responsible for implementing screening. They keep records on the number of informed and examined women in the screening, the final outcome of the screening, they monitor the implementation of clinical way and report to the department/Institute of Public Health once a month.

Women with positive cervical smear within the screening program are directed to further diagnostic procedures in accordance with the Guide for good clinical practice. The time period from the referral issuance from the health center to the examination in the health institutions of the secondary and tertiary levels should be as short as possible (no longer than two weeks). These medical institutions provide services required to complete the diagnosis and perform necessary treatment (consultative colposcopy, biopsy, surgical treatment, radiotherapy, chemotherapy, palliative care, etc.). These services are not part of screening, but the part of the routine services of these health institutions, but reporting on them is required for the analysis of the screening results.

#### 4.2.8. Local government

In coordination with the institutes and departments of public health, health centers, representatives of religious and ethnic communities, associations of citizens, the media, representatives of local governments perform actions to educate and motivate women to respond to the call for an organized screening program.

#### 4.2.9. The mass media

In agreement with the participants of organized screening, as well as with the Ministry of Health, the mass media play an important role in the process of education, motivation and increasing response of women, through activities: national and local media campaigns ("leaflets", brochures, posters, billboards, radio jingles TV spots, contributions to the website of the Ministry of Health and the Office for the prevention of malignant diseases, social networks, etc.); press conferences; press releases; interviews; and specially designed programs.

### 5. METHODOLOGICAL GUIDELINES FOR CERVICAL CANCER SCREENING

#### 5.1. Screening model in the Republic of Serbia

Cervical cancer screening is performed on the territory of the Republic of Serbia as organized decentralised program.

Target population: women 25-64 years of age.

Population coverage: tends to at least 75%.

Screening cycle: three years (after two negative findings within one year).

Screening test: cytological cervical smear (PAP test).

Screening implementation carrier: selected physician, medical doctor gynecology specialist.

Interpretation of smears: accredited cytological laboratories.

Triage test: colposcopy and/or HPV test according to the Guide for good clinical practice in diagnosing and treatment of cervical cancer.

The end of the screening process: the screening process ends with the recommendation based on PAP test.

Further treatment and monitoring: health centers, hospitals and clinical centers.

Quality control and final evaluation of screening process: the Office for the prevention of malignant diseases.

Announcing results, determining the dynamic and content of the follow-up, including referrals to further diagnostics are performed by the elected medical doctor gynecology specialist pursuant to the Guide for good clinical practice in diagnosing and treatment of cervical cancer from 2012/2013.

## 5.2. Information, education, communication and social mobilisation

Prior to the beginning of screening implementation it is necessary to define the strategy of information, education, communication and social mobilisation, operation plan for its realization and its time frame, as well as to determine persons responsible for performing the mentioned activities at the level of the Republic of Serbia and managing districts.

The strategy for municipalities covered by health center represents a part of annual action plan of the health center activities prepared by the team for screening coordination that submits it for adoption to the competent institute or public health department.

## 5.3. Identification of target population

Screening helps identify the target group of women, from 50 to 69 years of age. Screening evidence is based on the list of the insured by The Republic Department for health insurance and other citizens and their right to health protection, regarding the regulations determining the area of personal data protection.

Coordination team for screening implementation in a health center, in cooperation with the institute or public health department, prepares the target population list.

The screening excludes women treated for precancerous changes and cervical cancer and women with removed uterus (total hysterectomy) for benign reasons (fibroids etc.).

## 5.4. Invitation plan

The invitation plan is made by the institutes or public health departments in cooperation with health centers.

Health centers, in accordance with their personnel and spatial capabilities and the invitation plan, organize inviting and testing of women, providing them the possibility of testing off working hours.

The invitations should include at least the half of target population per year.

Appointments are made during morning and afternoon hours for synchronising personal and working duties of women called for screening.

## 5.5. Invitation

The invitation letter is delivered by mail.

The invitation letter includes:

- 1) invitation with the phone number of health centers in order to make an appointment for testing;
- 2) information on the purpose and importance of screening (information leaflet).

Inviting can exceptionally be done by telephone. In this case, the woman is given an information leaflet during testing.

Coordination team for the implementation of screening in a health center in agreement with the competent institute or the public health department, periodically (every one to two months) checks women's response to calls for screening, using screening records which is constantly updated.

Repeated invitation is forwarded in a period not exceeding six months from the date of the first invitation.

In case a contact is not established even after six months, health center is required to provide a direct call along with an invitation letter. If after attempting a direct call by the health center, contact is not established, the woman is excluded from screening and is invited in the next cycle.

## 5.6. Determining the exact testing time

Screening participants confirm participation and testing appointment by phone, SMS, email or in person.

## 5.7. Testing

On the given date women (hereinafter referred to as screening participant) with a letter of invitation reports to the service for health care of women in a health center. Responsible health worker accepts her, takes the invitation letter, performs recording and sends her to the appropriate clinic specific for screening (or the clinic of the selected physician, doctor of medicine specialist in gynecology, but separately from regular patients).

The selected physician, doctor of medicine specialist in gynecology performs the following actions:

- 1) receives screening participants who made an appointment;
- 2) provides necessary information about screening;
- 3) gives screening participants to sign a statement if she does not want to participate in screening;
- 4) take anamnesis;
- 5) fills out a standard protocol (clinical pathways) in paper or electronic form;
- 6) refers a screening participant to mammography in the mammography unit with instructions to take the record of previous mammogram if she has them;
- 7) informs screening participants about the examination results (if the result is negative, a screening participant takes over a written report at the health center, and the result can be given over the telephone; in the

case of a positive finding, screening participant is called within the period of no longer than three weeks) ;

- 8) suggests further diagnostic procedures to screening participants with positive mammographic findings with the recommendations of a specialist radiologist, and in accordance with the Guide for good clinical practice for the diagnosis and treatment of breast cancer;
- 9) reports weekly to the responsible person from the team for coordination in screening implementation at the health center on meeting the dynamics of the action plan.

#### 5.8. Cytological examination

Implementation of cytological examination of plates in an organized screening program, is performed in accredited cytology laboratories. Cytoscreeners interpret PAP smears as positive or negative, and every positive plate and 10% of negative (random sample for quality control), are examined by an accredited supervisor (a cytopathologist or a pathologist, a gynecologist or a biologist trained to interpret PAP smears), in accordance with the methodological guidelines for the operation of cytology laboratories.

The cytological laboratory reports to the health center and a selected physician, medical doctor specialist in gynecology on the results of smears, within three weeks from the date of the receipt of plates.

#### 5.9. Referring a screening participant with a positive PAP test to further diagnostics

In case screening ends with a positive PAP test result, it is necessary to perform diagnostic procedures within four to six weeks from the referral by the health center.

If a patient underwent biopsy, she with a histopathological finding reports to the selected physician medical doctor specialised in gynecology who, depending on the type of diagnosed change, acts according to the recommendations of the Guide of good clinical practice.

It is extremely important to realize appropriate communication with the screening participant at all levels of healthcare. It includes introductions to all possibilities and outcomes of treatment and acquiring an informed consent of the patient for further diagnostic procedures and treatment.

#### 5.10. Collecting data and reporting

Data on the target population, sent invitations, response to screening, results of screening tests, all the necessary diagnostic and therapeutic procedures make a database at the health center. This database is necessary for the monitoring and estimation of screening implementation.

Records of sent invitations, given invitations and response to testing is conducted by the team for coordination of screening implementation at the health center. Mentioned activities are performed by a medical technician pursuant to the recommended standards.

### 5.10.1. Standard protocol (clinical path)

Reporting on the screening results is based on the minimal data set which must be collected to calculate the process and outcome indicators of the screening program.

The data necessary for the assessment of screening efficiency are created in every stage of screening implementation, thus a standardized and coordinated way of their collection is required. In order to avoid data loss, they should be collected at the time of their appearance. Thus the screening uses the standardized protocol (clinical path) that monitors the screening participant through every screening stage, from the beginning to the end, which refers to invitation, all visits to the physician and other health workers, as well as to the performance and analysis of screening tests and other procedures included in the screening process at all levels of health care.

Data entry:

The protocol can be printed on paper, but the optimal data entry into the protocol is electronically which requires the following:

- 1) the existence of the protocol for the electronic data entry with accompanying software equipment;
- 2) the existence of computer equipment at every work place where a screening participant is;
- 3) network of all work positions, so that all screening performers have insight into the previous stage of the process;
- 4) connection with the institutes and departments for public health and the Office for the prevention of malignant diseases.

In case such system exists, all the data are entered only once at the work place where they occur, and the networking allows them to be available at all other work places, as well as to the centers for collecting data where through the databases they transform into the required indicators.

### 5.11. Indicators of program implementation

Screening indicators can be process and outcome indicators.

Process indicators are:

- 1) percent of women who responded to the invitation and reported to a health center after the first and following calls;
- 2) percent of women that underwent the test;
- 3) percent of inadequate tests;
- 4) percent of women's response to further diagnostic procedures and treatment;
- 5) percent of returned invitations;
- 6) percent of women that did not respond to delivered invitations;

Outcome indicators are:

- 1) percent of positive tests;
- 2) percent of patients with intraepithelial changes;
- 3) Percent of patients with diagnosed cancer and pathohistological type – disease stage at diagnosis.

Process and outcome indicators are the elements of periodical reports on performed activities at all levels, from health centers to the Ministry of Health.

Screening outcome indicators are the elements for planning further activities of the health system in order to decrease the incidence and mortality from cervical cancer.

#### 5.12. Quality assurance

Quality and success of the whole screening program in one country depends on the high quality of every step in the organized screening.

Each step of the screening must be explained in detail through instructions so the screening organization on the territory of one country could be as uniform as possible.

Social mobilisation requires adequate professional approach to greater population synced with demographic, social, educational and religious structure of the population. Special attention must be directed to marginalized groups and minorities. Inviting and informing during all screening stages must be conducted by ethnic, legal and moral principles, synced with educational and social status of women according to the instructions.

Uniform smearing sets and standards for transportation, coloring and keeping plates according to screening instructions are necessary.

In order to be accredited for screening, cytological laboratories must meet the criteria for space, equipment, personnel, organization and work quality control.

Uniform data collection through unique protocols and reports are necessary for monitoring and estimation of screening implementation.

Based on monitoring and estimation of screening implementation as collected data, quality control is performed on all screening stages: through response, mammography, reading of mammograms, supervisors and education.

#### 5.13. Monitoring and evaluation of screening

Monitoring and evaluation of screening is planned and conducted by the Office for early detection of malignant diseases through a database of organized screening and periodical reports of the public health institutes and centers. Final evaluation of the screening is done by the Ministry of Health for each calendar year, based on the data and reports of the Office for early detection of malignant diseases.

### 6. FINANCING

The National program for early detection of cervical cancer is financed pursuant to the law.