



Government of Montenegro
Ministry of Health

**Proposal of the
NATIONAL PROGRAM
FOR EARLY BREAST CANCER
DETECTION**

Podgorica, June 2010

INTRODUCTION

Breast cancer is the most common malignant tumor and one of the leading causes of death among women. Increase in the number of persons suffering from this disease is noted throughout the world: in the developed countries, as well as the developing ones.

Primary breast cancer prevention, that is, prevention of development of this disease is still of limited character, and the preventive activities are focusing primarily on early detection and optimum treatment of the disease.

With the help of the organized programs aimed at systematic early breast cancer detection (screening programs), as well as timely and adequate treatment in a large number of developed countries, in the past decade there has been a significant drop in the mortality caused by this disease.

Breast cancer screening represents organization of mammographic check-ups among healthy women of a specific age group, for the purpose of early detection of the disease, in the pre-clinical, early stage.

Mammography is sensitive in the detection of changes in breasts (it successfully detects changes, especially micro-calcifications related to early, non-invasive carcinoma – “in situ”, which cannot be detected with any other method), but it is not specific enough in the final definition of the nature of changes (a definite diagnosis cannot be set just based on the mammographic findings). Having in mind that today, in the developed world, one fourth of carcinoma in the “in situ” lesions stage are detected with the help of systematic screening, a huge importance is given to the socially organized approach to this issue. Mammography, which is recommended by the EU (Council Recommendation 2003/878/EC dated 02 December 2003 on cancer screening), proved to be efficient in case of women in the age group 50-69. In the United States, mammography is used among women starting from the age of 40, and this approach was also used by Sweden. The screening program can be successful only if, besides the activities aimed at early detection, there are conditions for adequate diagnostics, treatment and better quality of life of the diseased. The program of early breast cancer detection contributes significantly to the improvement of the health of the population and cost effectiveness is achieved only if it is well designed, if it covers the overall target population and if good quality of work is secured at all levels.

Organization of the program for early breast cancer detection is a multidisciplinary activity. The quality of the overall process (invitation, diagnostics, detecting suspicious lesions, therapy and monitoring) should be secured prior to initiating the program, and during its implementation it is necessary to work on continuous monitoring and quality improvements at all

levels and in all segments. Even the best prepared and controlled screening program cannot be successful without a strong political and financial support.

OVERVIEW OF THE CURRENT SITUATION

EPIDEMIOLOGICAL SITUATION

According to some assessments, in 2006, there were approximately 430,000 new women suffering from breast cancer detected, and almost 132,000 women died from this disease.

Increase in mortality caused by breast cancer was noted in the European countries in the 50's and 60's of the previous century. Then in the 70's and 80's, in some countries of the Western Europe, USA, Canada and Australia, there has been a halt in increase in death cases or the beginning of a downward trend. Just a few decades ago, they have initiated organized programs of early breast cancer detection. In Sweden, Finland, Norway and Great Britain, the implementation of similar programs resulted in the reduced mortality caused by breast cancer.

In Montenegro, breast cancer is the most common malignant tumor among women and the leading cause of cancer-related death among female population.

Since 1996, in the Clinical Center of Montenegro, there is a multidisciplinary consultation group of doctors (consisting of a surgeon, radiologist – diagnostician, pathologist, radiotherapist, and chemotherapist). Although the data is not fully reliable, due to non-existence of the adequate registration of malignant diseases at the state level, the data of the Consultation group for breast cancer show that there is an increase in the number of newly diseased women with breast cancer in the period 1996-2007, and in the past five years, according to the same Consultation Group, there is approximately 200 new cases of breast cancer detected annually.

<i>Year</i>	<i>1996</i>	<i>1997</i>	<i>1998</i>	<i>1999</i>	<i>2000</i>	<i>2001</i>	<i>2002</i>	<i>2003</i>	<i>2004</i>	<i>2005</i>	<i>2006</i>	<i>2007</i>
No of new cases of this disease	124	155	186	179	195	179	195	199	192	192	230	232

In the first four-year period (1996-1999), early breast carcinoma has been detected among 56% of the diseased women, and the advanced/metastatic disease was detected among 44% of the diseased. In that period, only 1.27% of in situ carcinoma were detected. In the last observed four-year period (2004-2007), there has been a significant increase in the breast cancer (72%), with the reduction in the share of advanced/metastatic stage of disease to 28%. In this period, the in situ carcinoma was detected among 2.36% of the diseased women.

The table below presents the number of women who died from breast carcinoma in Montenegro, in the period 1999-2007, according to data obtained from the Public Health Institute:

<i>Year</i>	<i>1999</i>	<i>2000</i>	<i>2001</i>	<i>2002</i>	<i>2003</i>	<i>2004</i>	<i>2005</i>	<i>2006</i>	<i>2007</i>
No of deaths	65	65	70	77	65	65	78	94	86

(Source: Statistical Yearbook)

A bit less than two years ago, in the Danilovgrad municipality a pilot project was initiated for early breast cancer detection, for women in the age group 50-69 and with the interval between check-ups of 2 years. The response of women with regard to mammographic screening was approximately 70%. This pilot project was expanded six months ago to include the female population from 40 to 49 years of age. The world experiences in the systematic screening, and the encouraging initial results of the pilot project represent the basis for the development and definition of the National Program for Early Breast Cancer Detection.

LEGAL REGULATIONS

The provision of Article 10 of the Law on Health Protection (Official Gazette of RoM no. 39/2004, and Official Gazette of MNE no. 14/10) defines the priority measures of health protection, including the activities for improvement of health and raising the level of health state of the population in Montenegro, health-related education with regard to the most common health problems and methods of their identification, prevention and control, timely detection, treatment and suppression of contagious, chronic, non-contagious and malignant diseases.

In December 2008, the Government of Montenegro adopted the Strategy for the prevention and control of chronic non-contagious diseases and the Action Plan for the first five years, in which one of the goals is to reduce mortality caused by malignant neoplasm, especially the ones with verified successful programs of early detection, and breast cancer is among them.

HR CAPACITIES AND EQUIPMENT

For the organization and implementation of the National Program for early breast cancer detection it is necessary to train the staff and to secure adequate equipment. It is necessary to hire public health services (epidemiology, statistics, development of a special breast cancer register, that is malignant neoplasm

register, to record all the newly diseased and monitor the results based on the stage in which the disease was identified and the type of treatment used), which involves the participation of the Institute for Public Health, as the main implementer of all these activities. Besides, it is necessary to develop screening registers as soon as possible, as this would enable adequate monitoring of the examined women, and part of evaluation of the program activities, by comparing the results achieved with the similar programs implemented in the region.

In the process of preparation and implementation of the Program, it is necessary to secure a sufficient number of quality, educated selected doctors, doctors who specialize in radiology and radiology technicians, trained specially for mammographic check-ups, as well as epidemiologists, surgeons and pathologists. .

In the primary health care there are currently 14 doctors specialized in radiology, while 9 doctors are currently undergoing specialized training in radiology, while the total number of radiology technicians is 54, out of which 20 have higher education, and 34 have a high school degree.

In Montenegro, there are 14 mammographic units: 11 in the health centers (Bar, Budva, Berane, Bijelo Polje, Danilovgrad, Kotor, Pljevlja, Podgorica, Rožaje, Tivat and Ulcinj), and one mammographic unit in the Clinical Center of Montenegro, in the General Hospital in Niksic and in one private health institution in Podgorica.

MONITORING OF THE QUALITY OF PERFORMANCE

Provision of the quality control is of utmost importance at all levels of implementation of the Program. The number of existing mammography units which belong to the analogue technology at the moment is sufficient.

The leading screening programs in both, Europe and in other parts of the world are being transformed or have already become transformed into digital mammography technology. DMIST study (50,000 women) in the USA found that digital mammography technology is superior compared to the analogue mammography for several specific sub-groups of patients, while the Norwegian paper Vestfold County established increased number of detected DCIS in general population that was subject to the screening. Digital mammography provides higher quality results in a more consistent manner than the analogue one which varies in terms of reliability and sensitivity. Digital mammography is essential for the flexibility of electronic communication and archiving of snapshots. For the above mentioned reasons, screening program based on mammography is to be implemented in the coming period. Mammography devices used in initiation of the Program are to be replaced by the high quality digital devices in the coming period.

It is important that the screening project follows establishment of the reference National Diagnostics Center at the Clinical Center of Montenegro which should also play its role in monitoring of the control of the quality of performance and evaluation of clinical performances of all mammographic centers in Montenegro. In order to ensure the reference role of the Diagnostics Centre for Breast Diseases at the Clinical Center of Montenegro, it has to be equipped with the state of the art equipment. That means one digital mammography device with tomosynthesis for definitive diagnosis.

It is also necessary to purchase a dedicated table with the possibility to conduct vacuum assisted stereotactic guided biopsies of non-palpable suspicious breast lesions. The selection of this equipment should be based on verified and proven practice gained so far under all large, fully digital European and American screening programs. Transfer of digital snapshots towards and from remote locations/centers for screening should be resolved by application of the latest technology by taking into consideration the factor price/the benefit of transfer through the internet or through the transferable storage systems. This is very important from the perspective of the lack of specialized staff at the beginning, since compensation is provided through the principle of teleradiology. Selected solution should have the possibility of future adjustment in line with development of technology which is available in Montenegro itself because these are public services.

For the same reason, the program must be equipped with the software for Computer-Aided Diagnosis (CAD) as well as with the software for quantifying breast tissue density, as a proven risk factor. These software solutions should be prioritized in implementation in becoming part of every mammography acquisition system, namely installation. In addition, it is also necessary to include magnetic resonance imaging in the diagnosis of breast pathology and find the most adequate solution in terms of quality.

Regional availability of screening examinations is important for the level of participation-response under the Program. It is recommended to install digital mammography equipment in three regional centers (for instance, in Berane for the Northern region, in Danilovgrad or Podgorica for the central region as well as in Kotor for the Southern/coastal region). So far, these centers have proved to be the best in organizing the screening.

The need for mobile mammography screening device should be evaluated and implemented if this solution is expected to have a positive impact on the level of response. Such digital mobile unit should be equipped with the solution for transferring snapshots towards and from the unit. Digital mammographic

equipment in the mobile unit should have usage permit which is in line with the use of mobile units in other European screening programs.

During implementation of the Program one should continuously insist on improvement of equipment and quality of performance which includes:

- a. adjusting the number of reading workstations at the central reading location to the total number of trained radiologists, as well as to the number of performed mamographies;
- b. harmonization of archive capacity with the increase in the number of digital mammograms and scanned mammograms;
- c. continued education and testing the knowledge of professional staff;
- d. development of solutions for transfer/storage of snapshots between the central reference center and remote centers (both, fixed and potential mobile);
- e. contracting equipment upgrade to bring it in compliance with the latest software versions, as well as maintenance of installed equipment.

Real scale of the problem will be demonstrated during implementation of the Program once the process of systematic breast cancer detection brings together several two-year cycles.

OBJECTIVES OF THE PROGRAM FOR EARLY BREAST CANCER DETECTION

1. Reduction of female mortality caused by breast cancer by 15% in the period of 5 years after the beginning of implementation of the Program;
2. Early detection of breast cancer above 80% (now it amounts to 72%) with the possibility to detect *in situ* lesions above 10% (now it amounts to 2.5%); which would reduce the costs of very expensive treatments of advanced/extended disease;
3. Improvement of the quality of life of female patients suffering from breast cancer.

TARGET POPULATION

Target population includes all healthy women in Montenegro aged 40-69 years, with the interval of examination in every two years. According to the MONSTAT data there are around 114,000 women in this group in Montenegro as on 01 January 2007.

AGE STRUCTURE OF FEMALE POPULATION IN MONTENEGRO aged 40-69 years

<i>Five year period</i>	<i>Aged 40-49 years</i>	<i>Aged 50-59 years</i>	<i>Aged 60-69 years</i>
<i>First</i>	21,703	21,620	13,463
<i>Second</i>	22,121	19,082	15,897
<i>total</i>	43,824	40,702	29,360
TOTAL	113,886		

SCREENING TESTS

1. High Quality Mammography

Mammography is x-ray breast examination which detects tumors, particularly those of small size in order to be able to touch them. It has been proven that mammography examination allows for early detection of tumors on average two years earlier than clinical examination based on symptoms or palpable lumps. Despite its outstanding value and irreplaceability in detecting malignant tumors, it is important to underline that mammography cannot determine up to 15-20% of cancers, especially when it comes to breasts with dense glandular structure.

2. Clinical Breast Examination

Clinical breast examination should be performed as part of regular preventive examinations every two years for women up to the age of 40, and after the age of 40 it should be performed each year (recommendation of the American Cancer Society). Clinical examination is performed by chosen physicians in the primary health care.

3. Breast Self-Examination

Breast self-examination is the process by which the woman reaching 20 years of age examines her own breasts once a month in order to gain insight into their condition and detect the existence of any irregularities in them. Self-examination is not sufficient method for early detection of breast cancer, but it is very important as it promotes awareness of women to be active in identifying this potential problem.

ORGANIZATION OF THE PROGRAM FOR EARLY BREAST CANCER DETECTION

The Program for Early Breast Cancer Detection is aimed at raising awareness about the breast cancer problem, early detection of signs and symptoms of the disease, ensuring high percentage of the coverage of women in the screening program (minimum 70%), as well as the obligation to guarantee adequate diagnosis and treatment of women with positive/suspicious results determined during screening examination.

1. There is a need to conduct continuous media campaign about the importance of prevention and early detection of breast cancer even before the start of the Program and also during implementation of the Program. As part of the general social mobilization, the above mentioned activities of education and motivations of women in relation to active approach to promoting their own health should also include non-governmental organizations, in addition to the health centers and the Institute of Public Health.
2. Additional training and motivation of staff in primary health care (selected physicians and nurses) is required in the areas of health promotion, encouraging women to have mammography and clinical breast examination. Selected physicians, radiologists and surgeons need to be educated about the standardized mammography terminology (BIRADS classification).
3. Invitations for mammography examination of women aged 40-69 years are sent from the health care centers to the home addresses on the basis of updated data of the Health Insurance Fund of Montenegro and the Ministry of Interior of Montenegro. Invitations are sent according to the schedule of available dates of the Support Centers at the health care centers (Centers for Rtg Diagnosis/Mammography Units), while the date and time of examination are stated in the invitation. In addition, the invitation contains number of the free phone line at the health care center through which it is possible to change the scheduled date of examination.
4. Together with the invitation letter, each woman receives a questionnaire to fill in. In addition, she also receives appropriate educational brochure prepared by the Ministry of Health. The brochure refers to what the woman needs to know about early detection of breast cancer, as well as the information on the manner of performing mammography examination. Implementation of this Program includes radiology specialist and x-ray technicians from the Centers for Radiological Diagnosis at the health care

centers. The Program features mammograms not older than 10 years and for which there is an appropriate decision on usage, that is Decision on performance of radiology related activities issued by the Ministry of Health of Montenegro.

Mammogram results are read within 2 weeks. In addition, it is also necessary to provide double independent readings of mammogram results.

The result is written in three copies in a specially prepared form: one remains with the radiologist, one is delivered to the woman and one copy is submitted to the Institute of Public Health. If the result of the screening examination is a negative one, that is communicated to the woman and she is also notified that she will receive invitation letter for the next examination in specified time period (in two years). In the event of positive or suspicious result, the woman is notified thereof by the selected physician who refers her to further diagnostic processing or determines a special monitoring regime for her. By issuing a separate decision, the Ministry of Health will designate centers that will perform additional diagnostics and surgical treatment.

It has been proven that 10-15% of breast cancers may not be detected by mammography. The woman confirms being notified thereof by signing the questionnaire.

The Ministry of Health sets up the Coordinating Body for organization, professional monitoring and quality control of the mammography screening program (hereinafter referred to as the Coordinating Body). Prior to initiation of the early detection of breast cancer program, the Coordinating Body provides training to radiologists, radiological technicians and other profiles of health workers participating in the early detection and treatment program; it draws up a list of radiologists certified to read results and prepares the plan of the quality control of examinations.

The Ministry of Health and the Institute of Public Health in collaboration with health care centers coordinate the organization of invitation of women, along with monitoring and evaluation of the Program. The coordinator in charge of these tasks is appointed in each health care center. It is also necessary to ensure permanent two-way communication between health centers, the Institute of Public Health and the Ministry of Health.

MONITORING AND EVALUATION OF THE PROGRAM

The Institute of Public Health, on the basis of reports from the health care centers, conducts regular monitoring and evaluation at the state level and notifies the Coordinating Body of the Ministry of Health thereof.

FINANCING OF THE NATIONAL PROGRAM

Montenegro will provide funds for implementation of the National Program from the state budget and from donors, however during the first year of implementation of the Program (2010) certain activities will be financed from current assets of entities responsible for implementation of activities (health care centers, general hospitals, the Clinical Center of Montenegro, Health Insurance Fund of Montenegro, Institute of Public Health and Ministry of Health). In the coming period, from 2011 onwards, the dynamics of providing and spending of funds designated for implementation of the National Program will be determined each year in the procedure of adopting the state budget. In order to implement certain measures from the National Program, their implementing entities, with the approval of the Ministry of Health and the Government of Montenegro, may conclude agreements with international organizations and other interested donors.