



Delegation to Montenegro

## Policy study

# Prevention and early detection of colorectal cancer in Montenegro

**Coalition for Social Changes**

Juventas

The Monitoring Center CEMI



**CEMI**

The project is funded by the European Union and managed by the EU Delegation to Montenegro. The project is implemented by the Monitoring Center CEMI.

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## Introduction

Within the framework of the project “Strengthening advocacy function of CSOs in Montenegro through developing policy-oriented capacities of Coalition for Social Changes”, implemented by the Monitoring Center - CEMI in cooperation with Juventas and Cazas, formed a Coalition for Social Changes, comprised by ten NGOs from Montenegro. This coalition has prepared recommendations for the improvement of policies in the areas of health, social care, employment and education, which are regulated by the Poverty Alleviation and Social Inclusion Strategy (PASIS). This document establishes a series of activities and measures with the aim of preserving and improving the health of citizens. To such an end, a set of laws and bylaws have been adopted, which regulate the prevention and control of chronic non-communicable diseases, including malignant tumors.

Achieving this goal includes measures of prevention and early detection of malignant neoplasms for which there are valid and acceptable screening tests: breast, cervical and colorectal cancers. Currently, prevention and early detection of breast and cervical cancer is being implemented in Montenegro, while the implementation of the legally established measures of prevention and early detection of colorectal cancer are not fully implemented.

Today, when we know that 80-95% of patients with colorectal cancer can be cured if diagnosed early through organized and effective system of early detection, it is expected that the implementation of the legally established measures, would have a significant impact in the reduction of morbidity and mortality caused by this disease.<sup>1</sup>

The recommendations of this study include measures that significantly contribute to improving the health of the population, because proper prevention enables detection of malignant colon tumors in the early and limited stage, i.e. in the stage of so-called pre-malignant lesions or early cancers, when the prospects for curing are great. In this way, health care is provided to all patients who are at risk of getting the disease, including the socially vulnerable, thus contributing to equitable healthcare.

For purposes of this study and other studies that monitor the implementation of PASIS, CATI (computer-assisted telephone interviewing) survey was conducted on a sample of 1050 citizens of Montenegro, who were asked to express their views on health, education, levels of social exclusion and employment policies in Montenegro. Further, in-depth interviews with representatives of medical institutions and decision makers in this area were conducted.

This study is structured in 5 chapters.

**The first part** gives a brief overview of institutions and organizations that are involved with the health policies in this area.

**The second part** provides an analysis of the normative framework regulating the prevention

<sup>1</sup> Rob Hicks, Trisha Macnair, „Bowel Cancer“, BBC Health, [http://www.bbc.co.uk/health/physical\\_health/conditions/in\\_depth/cancer/typescancer\\_bowel.shtml](http://www.bbc.co.uk/health/physical_health/conditions/in_depth/cancer/typescancer_bowel.shtml), January 2010, accessed on December 29th, 2010

ACS American Cancer Society, [http://www.fascrs.org/aboutus/press\\_room/backgrounders\\_and\\_tip\\_sheets/colorectal/](http://www.fascrs.org/aboutus/press_room/backgrounders_and_tip_sheets/colorectal/) accessed on December 10th, 2010

and early detection of colorectal cancer in Montenegro. Further, strategic documents that provide additional measures for regulating health policies are analyzed.

**The third part** presents the analysis of the situation, which contains a definition of colorectal cancer and the way health care is realized in terms of this disease. Special attention is paid to risk factors for colorectal cancer, classification of patients by degree of risk and the modalities of screening for these patients. Finally, this part provides an overview of the pilot project on the importance of early detection of colorectal cancer that was implemented in the municipality of Danilovgrad, by the Ministry of Health.

Comparative analysis of the prevention and early detection of colorectal cancer is provided in **the fourth part**, where it is demonstrated how this area is regulated in Serbia, Croatia and Bosnia and Herzegovina.

**The fifth part** of the study contains the summary of the study, with general assessment of the situation and specific recommendations for the improvement of policies regulating the prevention and early detection of colorectal cancer in Montenegro.

## **I Institutional framework**

### **1.1. State Institutions**

#### **Ministry of Health**

Ministry of Health as an umbrella institution for health issues in Montenegro organizes its activities through sectors and departments.

The Department of healthcare carries out activities related to the implementation of health policies, which regulate the general principles of the system in the areas of primary, secondary and tertiary health care. This department monitors the reports on health condition of the population prepared and submitted by the Institute for Public Health, and according to the reports, organizes measures in order to ensure adequate healthcare and monitors the implementation of laws and other regulations related to the health of population which are under the jurisdiction of the Ministry.

The Department for the management of healthcare, among other, implements activities related to the preparation of health policies, development and improvement of the health system through utilization of resources, management and organization, as well as supervises the work of the Health Insurance Fund.

The Department for European Integrations and International relations performs activities that are related to the implementation of activities and obligations of the Ministry within the process of accession to the European Union in the field of healthcare, providing information on the preparation and implementation of Action plans of relevance to the healthcare, definition of donor programs, cooperation with relevant bodies and institutions regarding the EU accession process and monitoring of the activities and obligations of the Ministry in the process of the EU accession.

#### **Institute for Public Health**

The Institute for Public Health (hereinafter the Institute) is a highly specialized health institution at the tertiary level of healthcare, which ensures the preservation and improvement of the health of all citizens of Montenegro.

In the field of prevention, the Institute monitors the implementation of preventive programs and to that aim coordinates the work of all health institutions in Montenegro. Additionally, the Institute analyzes and researches epidemiological situation of communicable and noncommunicable diseases of broader socio-medical significance, and proposes and implements measures in the field of preventive care. The Institute also collects and processes, in accordance with the Law on data collections in the field of health, defined health statistics, and manages health data of interest for the Republic. Activities of the Institute in the area of prevention also include epidemiology of communicable and massive noncommunicable diseases, as well as improvement of health-information system and health statistics.

Within the framework of this study, the Institute of Public Health is, according to the Law on data collections in the field of health, a competent body for the management of the Registry for malignant neoplasms.

### **Health Insurance Fund of Montenegro**

Health Insurance Fund of Montenegro is an institution that ensures the provision of health care rights and insurance, with the main goal of financing the health care of the entire population. As part of its activities, the Fund, inter alia, performs following activities:

- Prepares plans and programs for the implementation of development policies and improvement of healthcare, laws and other regulations on conditions, procedures and manner of exercising the rights to health care and health insurance
- Provides expert assistance to their beneficiaries and protects their interests
- Implements international agreements from the area of healthcare related to health insurance
- Concludes agreements with health institutions and other organizations in relation to the provision of health services to insured persons and monitors the implementation of such contracts.

### **Clinical Center of Montenegro**

Public health facility Clinical Center of Montenegro (hereinafter: the Clinical Center) is a highly specialized medical and scientific institution and teaching facility of the Medical University in Podgorica.

Clinical Center of Montenegro provides healthcare for the citizens in various fields, including internal medicine, general surgery, oncology and radiology, clinical genetics and laboratory diagnosis. Activities at the Clinical Center are carried out in organizational units, among which:

1. Intern Clinic, which includes the Department of Gastroenterology
2. The Center for Abdominal Surgery, which operated under the jurisdiction of the Surgical Clinic and includes the Department of colorectal surgery.
3. Oncology Clinic, which comprises of the Department of chemotherapy, Department of Radiotherapy and Nuclear Medicine Department.
4. Center for Medical Genetics and Immunology, which includes the Department of Medical Genetics and Department of Immunology
5. Center for Clinical and laboratory diagnosis which consists, among other, of the Department for biochemical Diagnostics as well as the Department for hematological diagnosis.

Scientific research activities at the Clinical Center are particularly diverted on clinical researches of specific pathological conditions, etiological factors and treatment of diseases and fundamental-medical research. Scientific research activities at this center are performed on the basis of established programs and projects, through previously established teams, examining the field of applied medicine through linking clinical work with research in the laboratory.

Clinical Center, as a teaching facility of the Faculty of Medicine provides the implementation of plans and programs of the University of Montenegro-Faculty of Medicine in accordance with the law, guidelines and directives of the European Union.



## II Normative framework

Ministry of Health, Labor and Social Care of the Republic of Montenegro, adopted in July 2007, Poverty Alleviation and Social Exclusion Strategy (hereinafter referred to as „PASIC”). This strategic document is based on the Strategy of Development and Poverty Alleviation, which was adopted by the Government of Montenegro in November 2003. The Ministry of Health, Labor and Social Care in January 2007, formed an expert group with the task of analyzing the degree of implementation of the Strategy of Development and Poverty Alleviation and evaluating the then current situation, and proposing the necessary policies and programs in terms of reducing the poverty of vulnerable groups in the areas of education, health, social protection and employment, in accordance with the international standards.

The project priority proposals of local and regional significance, provided by the municipalities to the Ministry of Health and Social Care, served as a basis for the PASIC.<sup>2</sup> The strategy was drafted in accordance with the Agenda of Economic Reforms and Development of Montenegro 2007-2011, Sustainable Development Strategy and the European Partnership Action Plan. Within the PASIC framework, the area of health is recognized as a priority in terms of the implementation for the period 2007-2011, while the planned activities are aimed at health promotion, disease prevention and strengthening of the principles of equality, accessibility and affordability, ensured within the framework of sustainable development.

According to the PASIC, the health care system of Montenegro ensures the preservation and improvement of the health of the population, achieved through the implementation of a series of activities and measures aimed at health promotion, disease prevention, treatment and rehabilitation of patients. The main goals defined by the PASIC, based on these principles are:

- **Preservation and improvement of public health**
- Defining national goals for reducing inequalities in access to health care system
- Improving the access to medical care for the disadvantaged
- Reduction of inequalities in the health care system through improvement of the health of vulnerable groups

One of the priorities of reform of health sector, as defined by the PASIC, is the change of attitudes towards health. This reform is based on the principles of health policies aimed at raising awareness of citizens on responsible patterns of behavior in terms of health. In addition, the document establishes that the provision of health care system needs to be ensured in the most acceptable and most equitable way, while its development needs to be harmonized with the development trends from European health care systems. Pursuant to the established reforms, the emphasis of the health policy is placed on the prevention of chronic noncommunicable diseases, as one of the leading causes of morbidity and mortality worldwide.

Within the framework of PASIC implementation, the Strategy for the Prevention and Control of chronic noncommunicable diseases<sup>3</sup> was prepared and the Law on data collections in the field of health care adopted.<sup>4</sup> Additionally, of importance for the implementation of PASIC goals of great

<sup>2</sup> Poverty Alleviation and Social Exclusion Strategy, Ministry of Health, Labor and Social Care, Podgorica, <http://www.minradiss.gov.me/biblioteka/strategije>, July 2007, accessed on November 15th, 2010

<sup>3</sup> Strategy for the Prevention and Control of Noncommunicable Diseases, Ministry of Health, Work and Social Care, November 2008

<sup>4</sup> The Law on data collections in the field of health care “Official gazette”, number 80/08

importance are previously passed the Law on health insurance<sup>5</sup> and the Law on health care<sup>6</sup> on health care, while for the latter an amendment is being prepared.<sup>7</sup>

The Government of Montenegro has endorsed in November 2008, the Strategy for the Prevention and Control of chronic noncommunicable diseases, which include following diseases: ischemic heart diseases, cerebrovascular diseases, malignant neoplasms, diabetes mellitus and chronic obstructive pulmonary diseases. This strategic document is in accordance with the European Strategy for the Prevention and Control of chronic noncommunicable diseases, drafted by the World Health Organization in 2006. The need for the preparation of this strategy in Montenegro is based on the following facts:

- In the structure of total mortality of the population in Montenegro, the share of chronic noncommunicable diseases is about 75%.
- The share of chronic noncommunicable diseases in the total incidence of Montenegrin population is increasing. This is primarily due to the aging of the population and the characteristic of society in transition, i.e. the socio-economic and environmental determinants of health which foster the practice of inadequate health lifestyles (patterns of behavior) among the population of Montenegro
- Significant loss of life age caused by premature deaths, as well as significant disability and absenteeism caused by chronic non-communicable diseases, represent a large economic burden for the state.
- Significant number of risk factors for the development of major chronic noncommunicable diseases has been identified, while many of these risks are preventable, mostly through practicing health lifestyles.<sup>8</sup>

According to Monstat, the Statistical office of Montenegro from 2006,<sup>9</sup> malignant neoplasms are, after cardiovascular diseases, a leading cause of death in Montenegro. In 2006, in Montenegro 974 persons died from malignant neoplasms. Among the most common causes of mortality from malignant neoplasms in Montenegro, colorectal cancer occupied second place for men (13.9%) and third for women (8.3%).

Objectives set by the Strategy for the Prevention and Control of chronic noncommunicable diseases include the reduction of morbidity and mortality from chronic noncommunicable diseases, including some forms of malignant neoplasms, as well as the improvement of quality of life. The realization of these objectives when it comes to malignant neoplasms is planned through the establishment of the National Program for the Prevention and Control of malignant neoplasms, which would include measures of primary prevention and early diagnosis of the disease as well as reduction of exposure to risk factors, particularly for malignant neoplasms for which there are valid and acceptable screening tests.

<sup>5</sup> The Law on health insurance „Official gazette“, number 29/05

<sup>6</sup> The Law on health care „Official gazette“, number 39/04

<sup>7</sup> The information on the implementation of PASIS, Ministry of work and social care, <http://www.minradiss.gov.me/biblioteka/strategije>, June 2010, accessed in November 2010

<sup>8</sup> The strategy for the Prevention and Control of chronic noncommunicable diseases, Ministry of Health, Work and Social care,

<sup>9</sup> Monstat, „Leading death causes according to gender in Montenegro“, 2006

With the aim of carrying out the planned reforms of the health system, the Government of Montenegro has developed following strategic documents: Health policy in Montenegro until 2020, which served as a basis for legislative, policy oriented and action programs, as well as the Strategy for Healthcare Development.<sup>10</sup> Furthermore, for the purposes of the implementation of Healthcare System Improvement Project, the World Bank loan was acquired. These funds ensure, inter alia, the development of primary health protection and improvement of secondary and tertiary healthcare sectors.<sup>11</sup>

Complementary to the aims of the Project, the following acts were adopted:

- Regulation on the extent of rights and standards of health care and mandatory health insurance (Official gazette, number 79/05),
- Protocol on standards, norms and ways of accessing primary healthcare protection through chosen team or chosen doctor (Official gazette, number 10/2008),
- Master plan for Development of Healthcare in Montenegro, for the period 2005-2010
- Master plan for Development of Healthcare in Montenegro, for the period 2005-2010<sup>12</sup>

With the adoption of the Protocol on standards, normative and ways of accessing primary healthcare protection through chosen team or chosen doctor, the necessary conditions for the implementation of the main goals of the Strategy for chronic noncommunicable diseases are established, furthered by the definition of certain obligations as defined by the Law on Health Care.

Article 1 of the Law on Health Care defines healthcare as a set of measures and activities aimed at preserving, protecting and improving health, prevention and control of diseases and injuries, early detection of diseases, timely treatment and rehabilitation. Consequently, **prevention and early detection** of diseases is associated with the implementation of prevention and early detection of cancer at the level of primary health care. More specifically, the Article 33 of this Law further defines health services that are implemented at the primary health care level and include:

- 1) Promotion of healthy lifestyles, including healthy nutrition of population
- 2) Detection, prevention and control of malignant diseases

In terms of malignant neoplasms, the objectives of the Strategy for the Prevention and Control of chronic noncommunicable diseases include screening tests for: breast, cervical, colorectal, prostate and skin malignant neoplasms. The Law on Health Insurance establishes additional medical measures and procedures of prevention, control and early detection of diseases, with special emphasis on providing the health care to persons suffering from malignant diseases (Article 17, paragraph 1, item 6). Furthermore, the Article 12 of the Regulation on the extent of rights and standards of health care and mandatory health insurance<sup>13</sup>, regulates services provided by the chosen doctor at the level of primary health care, which include preventive screening tests for early detection of cervical cancer (**PAP test**), breast cancer, as well as breast examination and mammography. Since **prevention and**

10 The Government of Montenegro, The Strategy for Healthcare Development, [www.mzdravlja.gov.me/files/1158667679.doc](http://www.mzdravlja.gov.me/files/1158667679.doc), 2003, accessed on November, 3rd 2010

11 Ministry of Health, <http://www.mzdravlja.gov.me/vijesti/37766/177975.html>, November 19, 2009, accessed on December 15 2010

12 Ministry of Health, <http://www.mzdravlja.gov.me/rubrike/strategija-razvoja-zdravstva-crne-gore/97487/MASTER-PLAN-RAZVOJA-ZDRAVSTVA-CRNE-GORE-ZA-PERIOD-2010-2013.html>, June 10th 2010, accessed on November 12th, 2010

13 Regulation on the extent of rights and standards of health care and mandatory health insurance, October 13, 2005

**early detection of colorectal cancer are not fully provided** in Montenegro, it is necessary on the one hand to extend the normative framework and on the other to implement existing legal provisions and integrate prevention and early detection of colorectal cancer into the primary health care system.

The adoption of a series of laws in the area of health imposes a need for the establishment of mechanisms which would regulate collection of data that is crucial for the monitoring of the field of health care, especially in terms of the prevention, monitoring and control of colorectal cancer. Calman-Hine report points out the importance of comprehensive data collection for cancer, which enables monitoring the effectiveness of prevention and treatment of this disease, as well as time trends related to the epidemiology of this disease.<sup>14</sup> In addition, the existence of a comprehensive data system for colorectal cancer enables precise determination of the etiology of the disease in a patient, which is of critical importance for both the prevention and control of the disease.<sup>15</sup>

While the Montenegrin legislation envisages the preparation of collection of data for malignant neoplasms – Registry, the legal liabilities however are yet to be applied. In result, the Registry for malignant neoplasms in Montenegro is still not established. On December 26th, 2008, the Law on data collections in the field of health care was adopted, which regulates that the data collections are used for the monitoring and the analysis of the public health, planning and programming of health care and for assisting government agencies in conducting health policies.<sup>16</sup> The Institute for public health is the competent body for managing the data collections, regulated by Article 4 of this Law. Register as a special data collection is maintained for diseases of major socio-medical significance and infectious diseases, including the malignant neoplasms (Article 9). In addition, Article 12 of this Law provides the establishment of data collections at the level of prevention within the non-hospital care. The law also regulates the procedures of updating the data collections, by which the healthcare providers are required to submit data from medical records to the body in charge of managing the data collections, through reports and statements, **including the reports on malignant neoplasms.**

For now, despite a clear, legally binding obligation, the Registry for malignant neoplasms in Montenegro has not been established. Although the development of the Registry is planned for this year, the lack of the Registry has broader implications, since it prevents the fulfillment of legal obligations, implementation of activities and achievement of goals that are established by the strategic documents. In accordance with the obligations set out by the Law on Health insurance, the abovementioned goals of the Strategy for the Prevention and Control of chronic noncommunicable diseases and the PASIS, it is obvious that the prevention and early detection of colorectal cancer have not yet been systematized in Montenegro.

### III Analysis of the current situation

According to the data of World Health Organization, set out in the European Strategy for the Prevention and Control of noncommunicable diseases<sup>17</sup> for year 2006, out of 150.322.000 people

14 Calman Hine report, April 1995, page 7 [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4014366.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4014366.pdf), accessed on December 5th, 2010

15 D Manser, D.F Levine, D.F.H Pheby, R.W Pitcher, “Colorectal cancer registration: the central importance of pathology”, April 19, 2000 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1731103/pdf/v053p00875.pdf>, accessed on November 19th, 2010

16 Article 2 of the Law on data collections in the field of health care, Official Gazette, number 80/08

17 Anna Ritsatakis, Peter Makara, „Gaining Health: Analysis of policy development in European countries for tackling noncommunicable diseases“, World Health Organization, Copenhagen, 2006. [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0018/105318/](http://www.euro.who.int/__data/assets/pdf_file/0018/105318/)

suffering from chronic noncommunicable diseases in Europe, 17.025.00 or 11% were diseased from malignant neoplasms. During the same year, out of total 9.564 million persons who died from the chronic noncommunicable diseases, 1.855.000 or 19% died from malignant neoplasms. Therefore, malignant neoplasms were in 2006, third in morbidity from all chronic diseases in Europe, after the diseases of circulatory system and neuropsychiatric diseases, and second in terms of mortality, after the diseases of circulatory system.

Due to the lack of the Registry for malignant diseases, it is not possible to determine either the prevalence or incidence of malignant diseases in Montenegro. Currently, the only source of data on the prevalence of this disease and the mortality rates in Montenegro are publications from Monstat. After cardiovascular diseases, malignant neoplasms are the most common cause of death in our country. According to MONSTAT, 974 persons died of malignant neoplasms in Montenegro in 2006, while 891 persons died in 2009, from same diseases.<sup>18</sup> The mortality rate for malignant disease in 2006 was significantly higher in males (573 or 58.8% for men: 401 women or 41.2%), while in 2009, a slight increase in mortality rates among was recorded (504 or 56.5% for male: 387 women or 43.5%). Additionally, the number of deaths from malignant neoplasms in Montenegro, in relation to the total number of deaths for the period from 2001 to 2006, it can be noticed that the number has not changed significantly. (Table 1)

**Table 1.** Mortality rate for malignant neoplasms 2001-2006

Year	The number of diseased and mortality rate in Montenegro in percentage					
	2001	2002	2003	2004	2005	2006
Malignant neoplasms	16,3	18,1	16,9	17,0	17,6	16,3

**Source:** Monstat

According to estimates of tumor incidence and mortality in Europe,<sup>19</sup> the standardized mortality rate for 2006 in Montenegro amounted to 209.3 for men and 119.3 women per 100,000 inhabitants (Table 2), while for the same year, in Serbia, total standardized mortality rate (for men and women) was significantly higher - 257, 8 (men) and 159.0 (women) per 100,000 inhabitants. Based on these data we can say that Montenegro belongs to a group of countries with medium-high mortality rate from malignant neoplasms for men and a low mortality rate for women.

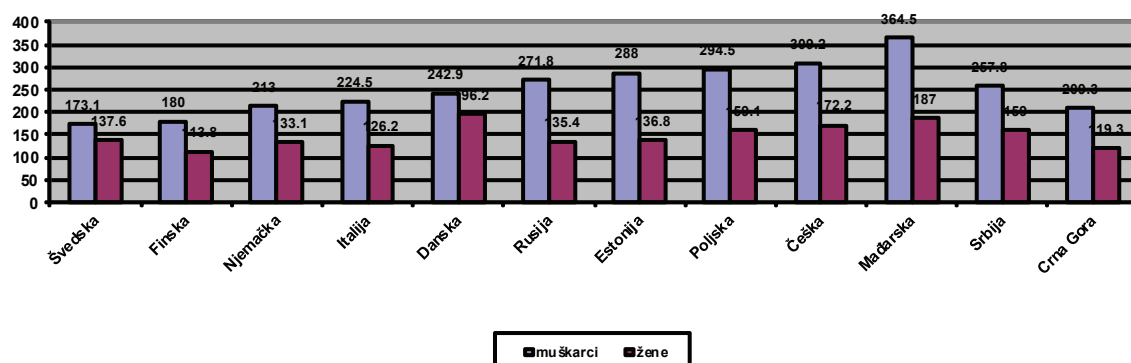
e92828.pdf, accessed on December, 5, 2010

18 Statistical office of Montenegro - Monstat, "Montenegro in numbers", Podgorica 2010

19 J Ferlay, P Autier, M Boniol, M Heanue, M Colombet and P Boyle, „The estimates of cancer incidence and mortality rates in Europe“, *Annals of Oncology* 2007, Volume 18, No 3: 581-592



**Tabela 2.** Standardizovana stopa mortaliteta 1:100.000 od malignih neoplazmi u izabranim evropskim državama



According to the available data from health statistics for year 2006 in Montenegro, the rate of malignant neoplasms in the number of people who were treated in hospitals is very high. With a share of 8.7% of all cases of hospital discharges, malignant neoplasms represent the fourth most common reason for hospitalization in 2006. In 2009, colorectal cancer represents 9.5% of all hospital discharges for malignant diseases.<sup>20</sup>

Consequently, malignant neoplasms represent a significant burden of the health system, primarily due to costs of hospitalization and treatment of primary malignancies and metastases of the disease.

### 3.1 Colorectal cancer

The two main characteristics that define cancer are uncontrolled growth of cells and tissue invasion. Uncontrolled cell growth without the tissue invasion is a characteristic of benign neoplasms. Malign neoplasms of epithelial tissue are called carcinomas, while malignant neoplasms of mesenchymal tissues are called sarcomas. Colorectal cancer is a disease where cells lining the colon and rectum become abnormal and begin to divide without control, forming a mass called tumor (colon and rectum are parts of the digestive system of human body). During this process, colorectal cells invade and destroy the surrounding tissue, and can also spread into the lymph system and bloodstream, after which the disease becomes incurable and leads to death.

Tumors with distal spread of 15 cm or less (measured by the rigid proctoscopy) from the anal margin are classified as rectal, while proximal from such border are tumors of the colon. The most common site of metastasis of colorectal cancer is the liver. The diagnosis of colorectal cancer requires a biopsy during rectosigmoidoscopy or colonoscopy and histopathological confirmation.

Colorectal cancer represents a major health problem due to the high incidence, which in the most countries over the past three decades is on the rise. According to the data from American Cancer Society (hereinafter referred to as ACS) for 2010, colorectal cancer is the third most common type of cancer in men (after prostate and lung cancers) and women (after breast and lung cancers). Additionally, colorectal cancer is the second leading cause of death of all malignant neoplasms in the US. During 2009 in the US, 146.970 new cases of colorectal cancer were registered (106 100 cases of

<sup>20</sup> Response to a request for access to information, number 01-8016.

colon cancer and 40.870 cases of rectal cancer), while 49.920 people died from this disease.

As noted above, due to the lack of Registry for malignant diseases it is not possible to determine the prevalence, incidence and mortality rates for colorectal cancer in Montenegro. Such data exists only for 2006, where the disease ranks as second in men and third among women in terms of incidence and cause of mortality in our country. (Table 3)

**Tabela.3** Najčešće maligne neoplazme kao kao uzrok smrti kod muškaraca i žena, Crna Gora, 2006.

	Men		Women	
Localization	mortality	/	Localization	mortality
Pluća	74,9		Dojka	27,8
Kolorektum	15,0		Pluća	21,0
Prostata	15,0		Kolorektum	7,4
Stadardized rate	100000			

**Source:** Monstat

### 3.1.1 Colorectal cancer and Healthcare system in Montenegro

Diagnosis and treatment of patients with colorectal cancer in Montenegro is performed in institutions of secondary and tertiary health care. Subspecialists gastroenterologists perform examinations of patients referred by chosen doctors from Health Care Centers, and in accordance with current clinical practice guidelines, refer patients to invasive endoscopic diagnosis that includes colonoscopy. Invasive endoscopic diagnostic endoscopy is performed by the gastroenterologist in laboratories, while in the case of diagnosis of colorectal cancer, further evaluation and treatment of the disease is in the competences of gastroenterologists, gastrointestinal surgeons and oncologists.

The National Program for the Prevention and Control of malignant neoplasms has not been established in Montenegro, which would include measures of primary and secondary prevention of colorectal cancer, although the adoption of such a program is presumably planned for the third quarter of 2011. Preventive examinations undertaken by the chosen doctors at the primary health care, which do not include examinations of patients with previously diagnosed colorectal cancer, are foreseen by the Article 33 of the Law on Health Care and the goals of the Strategy for the Prevention and Control of chronic noncommunicable diseases, but not implemented. The implementation of preventive screening for the prevention and early detection of colorectal cancer can also be achieved through expansion of the Article 12 of the Regulation on the extent of rights and standards of health care and mandatory health insurance. In this context, the proposals provided in this study are complementary to aspirations for the establishment of an adequate system of prevention and early detection in the general population with an average (normal) risk of developing colorectal cancer, as well as for the persons with an increased risk of developing this disease.

The best way of treating cancer is the primary prevention, i.e. prevention of the development of disease through the elimination of harmful effects or by promoting positive behavior patterns. Health education, proper diet and lifestyles and other measures of primary and secondary prevention can

reduce the incidence of colorectal cancer, and in most cases the disease can be detected at an early stage when treatment results are significantly better. Researchers estimate that the application of all that is known about the cancer prevention can help prevent the development of these diseases in nearly two-thirds of the cases.<sup>21</sup>

The prevention of cancer however is not always possible, since not all causes for the development of this disease are known or avoidable. Consequently, secondary prevention or early detection is still of great importance. When the disease occurs, the success of the treatment depends primarily on the degree of expansion of the disease at the moment of the diagnosis. On the basis of existing evidence on the effectiveness and the utilization of available methods for early detection, screening programs for cervical, breast and colon cancer are now generally accepted and recommended.

Symptoms that indicate the existence of colon cancer are occult or overt bleeding, changes in the intestinal emptying, weight loss, abdominal pain and anemia. Patients who have some of these symptoms are not included in the screening program, but are instead redirected for diagnosis.

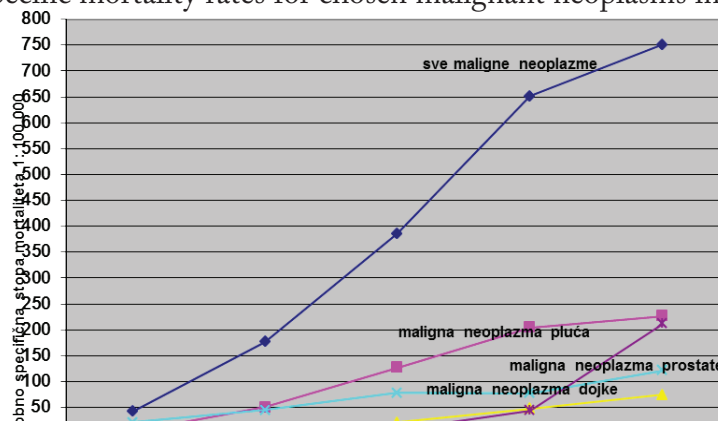
### 3.2 Risk factors for developing colorectal cancer

The exact causes of colorectal cancer development are unknown. However, studies have shown that certain risk factors are associated with an increased chance for developing this disease, including the following:

**Age:** Colorectal cancer is more common in older people. Although the disease can occur at any age, most patients with colorectal cancer are over 50 years of age. The risk of developing colorectal cancer increases significantly after 40 years of age, while 91% of all cancers are detected in people older than 50 years.<sup>22</sup> Every person over 50 years is at 4.8% of risk of suffering from colorectal cancer by 74 years of age, or at 2.3% of risk of dying from colon cancer.

According to Monstat, the age specific mortality rates of the colorectal malignant neoplasms are somewhat more evenly distributed with a significant increase only after the age of 65. Thus, from the total number of deaths caused by the colorectal malignant neoplasms, 38.2% died before the age of 65 and 73.5% before the age of 75 years of age.

**Tabela 4.** Age specific mortality rates for chosen malignant neoplasms in Montenegro, 2006 .



21 Cornuz J, Auer R, Senn N, Guessous I, Rodondi N. „Prevention and Screening“, National Health Institute USA, December 2010.

Otto S. Lin „Early detection improves chances to beat colorectal cancer“, Institute for digestive diseases, Virginia, 2003

22 Ibid.



## Polyps:

Polyp is a tissue mass that juts out into the lumen of the intestine, and represents the most common benign tumor of the colon. Polyps are classified as neoplastic or adenomas, which have a malignant potential and nonneoplastic polyps. The asymptomatic form is present in 12% of the population, while in people aged over 70 years up to 40%. The incidence of neoplastic polyps-adenomas is parallel to the incidence of colon cancer. All adenomas sooner or later transform into cancer, which is a well-known “adenoma-carcinoma sequence” that lasts on average 7-10 years. This means that most colorectal cancers have a slow genesis and that there is enough time for polyps to be removed through measures of secondary prevention, before the malignant transformation, resulting in the cease of “adenoma-carcinoma sequence”.

Familial adenomatous polyposis is an autosomal dominant mutation of tumor suppressor gene (APC), from chromosome 5p. Familial adenomatous polyposis is responsible for about 1% of colon cancer, and this syndrome includes Gardner’s and Turcot syndrome. In adolescence, some 100 and often even 1000 adenomas are developed in colon, which are always present in rectum. The patient usually dies from the colon cancer before the age of 40.

Nonneoplastic polyps are very common, especially metaplastic, which account for 75% of polyps in patients over the age of 40. This group includes inflammatory as well as familial hamartomatous polyposis syndrome (juvenile polyposis and Peutz-Jeghers syndrome).

Peutz-Jeghers syndrome is an autosomal dominant inherited disease characterized by intestinal hamartomatous polyps in junction with mucocutaneous pigmentation. Patients with Peutz-Jeghers syndrome are at a 15 times greater risk of developing intestinal cancer than general population.

Juvenile polyposis occurs in the first decade of life, and is inherited in an autosomal dominant (SMAD4 gene mutation). Juvenile polyps are usually localized in the rectum. In solitary polyps there is no significant risk for developing cancer, but with multiple polyps (>5), colon polyposis syndrome carries 10% of risk for the cancer development.

Hereditary nonpolyposis colorectal cancer (HNPCC) is an autosomal dominant genetic condition, present in 2-5% of patients suffering from colorectal cancer. There is no case of polyposis development.

23

**Personal anamnesis:** A person who is already diagnosed with colorectal cancer is at an increased risk of developing colorectal cancer for a second time. Studies have also demonstrated that some women with a history of ovarian, uterine or breast cancer have a higher chance of developing colorectal carcinoma.

**Family anamnesis:** First-order relatives (parents, twins or children) of a person who has had a colorectal cancer in most cases will develop this form of cancer, especially if a family member had cancer at an early age. In the case of a large number of patients from the family diagnosed with this disease, the chances of developing colorectal cancer increases even more. One quarter (25%) of patients have a family anamnesis of colorectal cancer, of which 15% are of first-order relatives.<sup>24</sup>

23 Donna Myers „ Colon polyps and cancer risk“, February 2007

Obren Popović, Mihajlo Božanić , „Polyps and colorectal polyposis” Interna medicina, 2003

24 Simona Valean, P. A. Mircea, Doinita

Crisan, Magda Petrescu, “ Sporadic Colorectal Cancer or Hereditary Lynch Syndrome: Anamnestic Epidemiologic Study Using

**Diet:** Many studies indicate that the development of colorectal cancer may be associated with an increased intake of red and processed meat, as well as the low intake of whole grains, fruits and vegetables.<sup>25</sup> Of all the external factors, nutrition is given utmost importance. David Burkitt in 1970 has pointed out that rural Africans suffer from much less colon cancer than the urban population of the United States. Through the examination of geographical distribution of colorectal cancer, the importance of nutrition in the development of colorectal cancer has been further outlined. Burkitt noted that the nutrition of the population of countries with the high risk for developing the colorectal cancer is dominant in refined carbohydrates, fats and meat products while lacking in the intake of fresh fruits, vegetables and foods rich in cellulose and fibrous materials.<sup>26</sup> In developing countries or countries with lower incidence of colorectal cancer eating habits are significantly different, with population having more frequent emptying of the colon and voluminous stool, which can have a protective role in the development of colon cancer. Recent research has demonstrated a significant protective role of fresh fruits and vegetables, fish, poultry meat, fiber, broccoli and cabbage, as well as the direct link between fat intake from animal sources and red meat, and an increased risk of developing colorectal cancer.

**Obesity:** Obesity, defined as body mass index (BMI) greater than 30kg/m<sup>2</sup>, is associated with about 10% of all cancers.<sup>27</sup> BMI is with both men and women in significant direct correlation with and increased incidence and mortality rate for cancers of the esophagus, stomach, colon, gallbladder and pancreas. Interestingly, the effect of obesity in women is much more pronounced during the premenopausal age, whereas the incidence of colorectal cancer is twice as high in obese persons. This correlation is lost at the start of menopause. The relative risk of developing colorectal cancer is about 50% higher in obese men and women.<sup>28</sup>

**Physical activity:** Research suggests that physical inactivity may be associated with an increased risk of developing colorectal cancer. Conversely, people who exercise are at a lower risk of developing colorectal cancer. A large number of studies that analyzed nearly 13.000 people indicate a clear inverse correlation between physical activity and colorectal cancer. The relative risk for the development of colorectal cancer in people who regularly practice physical activity is about 50% lower than in the general population. Further, it is believed that the effect of physical exercise is higher in men and is applicable not to the rectum, but other part of the colon. The exact mechanism of how the physical activity prevents this cancer is not known.<sup>29</sup>

**Smoking:** Tobacco use is the single most preventable cause of cancer in the world. It is estimated that smoking is the cause for 30% of the total deaths from malignant diseases.<sup>30</sup> The results of epidemiological studies suggest that cigarette smoking increases the risk of developing colorectal

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Amsterdam and Bethesda Criteria”, *BTCC Journal*, April 2010.

Judith Karner-Hanusch, Martina Mittlböck, Thomas Fillipitsch, Friedrich Herbst, „Family history as a marker of risk for colorectal cancer: Austrian experience“ *World Journal of surgery*, 1997

25 Bruce WR, Wolever TM, Giacca A, “Mechanisms linking diet and colorectal cancer: the possible role of insulin resistance.“ *University of Toronto, Canada*, <http://www.ncbi.nlm.nih.gov/pubmed/10965515>, 2000, accessed on December 24th 201

26 Burkitt, D., “Causes of disease“ *Lancet*, 1969. 2: p. 1229–1231.

27 Deckelbaum RJ, Fisher EA, Winston M, Kumanyika S, Lauer RM, Pi-Sunyer FX et al. “Overview of current issues in nutrition“, 1999; 100: 450-456.

28 Parkin DM, B.F., Ferlay J, Pisani P „Global cancer statistics: Globocan 2000. *Int J Cancer*, 2001. 94(2): p. 153-156

29 Meyerhardt, Jeffrey, Giovannucci Edward. „Physical Activity and Survival After Colorectal Cancer Diagnosis“, *Journal of clinical oncology*, August 2006. *godine*,

30 WHO. Cancer prevention. Available at <http://www.who.int/cancer/prevention/en/>

cancer.<sup>31</sup>

Primary prevention of colorectal cancer, which includes promotion and recommendation to reduce the preventable risk factors for the development of colorectal cancer and maintaining healthy lifestyles, including proper nutrition, reduction of obesity, moderate physical activity, is being implemented during the first examination by the chosen doctor, as well as organized programs and strategies at the national level.

### **3.3 Classification of patients according to the degree of risk for the development of colorectal cancer**

Based on the Practical clinical guidelines in oncology from 2009 – NCCN (National Comprehensive Cancer Network), classification of patients according to the degree of risk for the development of colorectal cancer is established: 1) the average risk and 2) with an increased risk.

I) Patients with an average risk of developing this disease include people from the age of 50 and older, with no symptoms, no history of existence of adenoma and colorectal cancer, inflammatory bowel disease and no family history.

II) The group of patients with an increased risk of developing colorectal cancer include people with inflammatory bowel disease (chronic ulcerative colitis, Crohn's long-term disease with colon cancer), genetic history (hereditary nonpolyposis colorectal cancer - HNPCC), familial adenomatous polyposis (FAP), including Gardner and Turcot syndrome, Hamartomatous polyposis syndromes (Peutz-Jeghers syndrome, juvenile polyposis), positive family history of colorectal cancer, colorectal adenoma, and a personal history of colorectal cancer, colorectal adenoma and breast, ovary and uterus cancer for women.

Considering that the paragraph 2, Article 2 of the Regulation on the extent of rights and standards of health care and mandatory health insurance defines priority measures on the detection and elimination of risk factors of certain diseases, including malignant neoplasms, for the entire population, within the framework of this study modalities of screening for the prevention and early detection of colorectal cancer are proposed, based on the patients' classification according to the degree of risk for the development of colorectal cancer

### **3.4 Measures of secondary prevention of colorectal cancer**

Secondary preventive measures of colorectal cancer include screening tests with the goal of detection and removal of adenomatous colon polyps and detection of colorectal cancer in early (asymptomatic) phase. For screening measures to be socially acceptable, they must have an adequate degree of sensitivity and an acceptable price. Digital rectal screening is the cheapest method, but this method of screening detects only 10% of colorectal cancer incidences. Flexible rectosigmoidoscopy can detect about 50% of cases, while colonoscopy can detect up to 95% of colorectal carcinomas. Secondary prevention measures today in developed countries are given more and more attention, given that the adequate implementation can significantly reduce the incidence of colorectal cancer and significantly improve the treatment results. Most commonly used methods of screening are fecal occult blood test and colonoscopy.

31 Edoardo Botteri, Simona Iodice, Vincenzo Bagnardi, "Smoking and colorectal cancer", Journal of American Medical Association, <http://jama.ama-assn.org/content/300/23/2765.abstract> 2008, accessed on January 10, 2011

## Fecal occult blood test

Testing for the presence of occult blood in the stool is used to diagnose occult (invisible to the naked eye) blood in the stool. This test is based on the fact that the blood vessels on the surface of larger colorectal polyps or cancers are usually more fragile or more easily damaged during the passing of feces. Damaged blood vessels release a small amount of blood in the feces, which mostly cannot be noticed through the inspection of stool. Occult blood test detects blood in the stool through chemical reaction. Guaiac impregnated slide test has a sensitivity of 30-50%, so two samples each need to be taken from three consecutive stools. Immunohistochemical test has a sensitivity of 90%, so one sample is sufficient and does not require dietary restrictions.

This test cannot determine whether the bleeding originates from the colon or other gastrointestinal tract (e.g. stomach). If this test is positive, it is necessary to do a colonoscopy in order to determine whether the cause of bleeding is cancer, polyp or for instance, boil, hemorrhoids, diverticulosis (small pouches that form in weak parts of the colon wall), or inflammatory bowel disease (colitis).

Early detection of colorectal cancer by testing on the presence of occult blood in the stool in asymptomatic average risk population, proved to be a suitable method because of its simple application and low cost. In a large population and controlled studies, a positive test had between 1% and 5% of respondents. A positive test is an indication for further gastroenterological testing or colonoscopy. The predictive value of positive test in colorectal cancer is 5-10% and 20-30% for adenomas. People who were tested for the presence of occult blood in the stool should be warned that a negative test does not mean that the person does not have polyps or colon cancer. Experience in the application of the test for fecal occult bleeding, as a screening test for early detection of colon cancer, conducted in the United States, Great Britain, Sweden and Denmark led to a decline in relative mortality rates of colorectal cancer to 18-33%.<sup>32</sup>

## Colonoscopy

Colonoscopy is a modern diagnostic method by which doctors can directly examine the entire colon. This procedure is performed using a colonoscope, a flexible, sterilized instrument of finger width, which due to its flexibility and optical fiber provides safe and accurate review of the entire colon. Colonoscopy can be performed with the use of mild sedatives (drugs, tranquilizers), analgesics (pain medications), and even with anesthesia. Examination takes 30-60 minutes, depending on the length and position of the colon. After the examination, the patient feels discomfort in the form of bloated abdomen.

Colonoscopy allows for direct mucosal inspection of the entire colon, while simultaneously enables taking of biopsy samples or definitive treatment by polypectomy in the case of precancerous polyps and some malignant neoplasms in the early stages. In contrast to this, all other forms of screening, if positive, require colonoscopy as the follow up procedure. According to the American Cancer Society, research has shown that most patients preferred colonoscopy over other invasive diagnostic methods.

33

Colonoscopy has its deficiencies. It is an invasive procedure and a large percentage of patients

32 Zoran Krivokapić, "Early detection of colorectal cancer", <http://www.medicom.com/content/view/282/64/>, October 2009, accessed on January 13, 2011

33 Schroy PC 3rd, Lal S, Glick JT, et al. "Patient preferences for colorectal cancer screening: How does stool. DNA testing fare? ", 2007;13:393-400.

prefer non-invasive method of screenings for colorectal cancer. The efficiency of colonoscopy depends on the preparedness of the patient for review, as well as on the training of endoscopist to perform the procedure. Studies have shown that the percentage of false negative results of colonoscopy in terms of large adenomas (= 10 mm) ranges from 6% to 12%.<sup>34</sup> The percentage for cancers is about 5%.<sup>35</sup>

Endoscopic procedures in addition to diagnostic can also be treatment methods. Colonoscopy, if the preparation is adequate and endoscopists trained can detect 90-95% of cases of malignant neoplasms, so today colonoscopy represents a „golden standard” for screening and diagnosis of cancer.

### 3.5. The modalities of screening for people at average risk of developing colorectal cancer

The modalities of screening for people at average risk of developing colorectal cancer, according to the National Guide for doctors in primary health care for the prevention of cancer of the Ministry of Health of the Republic of Serbia includes the necessary risk stratification based on family and personal history.<sup>36</sup>

a) To all persons older than 50 years, who do not belong to any group at risk, it is necessary to offer participation in programs of early detection of colorectal cancer. /IA/<sup>37</sup>

b) The optimal method of screening is the fecal occult blood test. /IIaB/

c) Persons who have no family history of colorectal cancer need to be tested annually for the presence of occult blood in the stool. /IIaB/<sup>38</sup>

d) Persons with a positive test need to be referred to a secondary level institution, where colonoscopy is to be performed.

e) Persons who express a desire to undertake endoscopic screening should be referred to an institution of the secondary level to undertake flexible rectosigmoidoscopy, once every 5 years.

Experience in the application of the fecal occult bleeding test, as a screening test for early detection of colon cancer, conducted in the United States, Great Britain, Sweden and Denmark led to a decline in relative mortality rates of colorectal cancer to 18-33%.<sup>39</sup>

In Montenegro systematic preventive examinations at the primary health care level for early detection and prevention of colorectal cancer are not implemented for groups of patients with an average level of risk for the development of this disease.

34 Rex DK, Cutler CS, Lemmel GT, et al. “Colonoscopy”, *Gastroenterology* 1997;112:24–28..

35 Bressler B, Paszat LF, Vinden C, et al. “ Colonoscopic miss rates for right-sided colon cancer: a population-based analysis”, *Gastroenterology*, 2004;127:452–456.

36 Each recommendation is stratified according to international standards, with Roman numbers I, II, IIa, IIb and III, while the degree of proof is classified with letters A, B and C.

37 Proof or general consent on whether the given treatment or procedure is useful or efficient. The data is based on multiple randomized clinical studies or meta-analysis.

38 Proof or an opinion that is in favor of usefulness and effectiveness of the proposed measures. The data is based on one randomized clinical study or broad nonrandomized study.

39 Zoran Krivokapić, “ Early detection of colorectal cancer”, <http://www.medicicom.com/content/view/282/64/>, October 2009, accessed on January 13, 2011. godine



### 3.6. The modalities of screening for people at an increased risk of developing colorectal cancer

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Modality of screening for people with a genetic load for the occurrence of colorectal cancer (NHPCC, FAP, juvenile polyposis and Peutz-Jeghers syndrome) according to the National Guide for doctors in primary health care for the prevention of malignant diseases of the Ministry of Health of Serbia, includes a series of measures that ensure early detection and prevention for patients with the higher risk of developing this disease.

1) Persons and members of their families who are, based on the family anamnesis and clinical analysis, diagnosed with one of the abovementioned syndromes, need to be recorded into the registry by the family doctor /IIaB/

2) It is necessary to refer these persons to a specialist of the tertiary institution, where molecular analysis will determine the presence of one of the mentioned syndromes. Additionally, persons with proven molecular disorders and members of their family need to be registered in the National Registry for hereditary tumor syndromes. /IIaB/

3) HNPCC (hereditary non-polyposis colorectal cancer)

- Colonoscopy once every 2 years starting at the age of 25 or 5 years younger than the age of the youngest cousin who is suffering from the colon cancer if that person is younger than 25. Monitoring is discontinued at the age of 75 or earlier if the absence of molecular mutations responsible for the development of the syndromes is confirmed. / IIaB /

4) FAP (familial adenomatous polyposis)

- For family members where genetic mutations cannot be detected, it is necessary to perform sigmoidoscopy annually starting from the age of 13 to 15 until the age of 30, and then once every 3 to 5 years until the age of 60. / IIaB /

- For family members where the existence of multiple adenomatous polyps or APC gene mutations are detected, preventive surgery of colon should be advised at the age between 16 and 20. / IIaB /

5) PJS (Peutz-Jeghers syndrome)

- Colonoscopy is recommended once every three years, starting at the age of 18. / IIbB / <sup>41</sup>

6) JP (juvenile polyps)

- Colonoscopy is recommended once every 1 to 2 years, starting at the age of 15 to 18 or earlier if symptoms occur. / IIaB /

Recommendations for people with a positive family history of colorectal cancer, according to the clinical practice guidelines in oncology (National Cancer Comprehensive Network) for 2009 include:

1) For persons who have first-order relatives suffering from colorectal cancer aged between 50-60

<sup>40</sup> This group does not include persons diagnosed with inflammatory bowel disease.

<sup>41</sup> Usefulness and efficiency of the proposed measures is less based on evidence or opinions. The data is based on randomized clinical trials or extensive nonrandomized study.

years, colonoscopy is recommended from 40 years of age, which is repeated every 5 years.

2) For persons who have first-order relatives suffering from colorectal carcinoma aged <50 years, a colonoscopy is recommended at the age of 40 or 10 years younger than the youngest member who is suffering from colorectal cancer. Colonoscopy should be repeated every 3-5 years.

3) For persons who have first-order relatives suffering from colorectal cancer at the age >60, colonoscopy is recommended starting at the age of 50, and should be repeated every 5 years.

4) For persons who have two first-order relatives diseased from the colorectal cancer at any age, colonoscopy is recommended at the age of 40 or 10 years younger than the youngest member who is suffering from colorectal cancer. Colonoscopy should be performed every 3-5 years after initial screening, depending on other familial predispositions.

5) For persons who have two second-order relatives diseased from the colorectal cancer at any age, colonoscopy is recommended at the age of 50, and should be repeated every 5 years.

6) For persons who have one first-order relative or one or more third-order relatives who are suffering from colorectal cancer, including first-order relatives suffering from noninvasive adenomas should be treated as patients with an average risk. Colonoscopy is the preferred screening method.

In Montenegro systematic preventive examinations at the primary health care level for early detection and prevention of colorectal cancer, are not implemented for groups of patients with genetic load for the development of colorectal cancer.

### **3.7. Pilot project for early detection of colorectal cancer in the Municipality of Danilovgrad**

Ministry of Health and the Health Care Center Danilovgrad are implementing a pilot project - Program of early detection of colorectal cancer. This program covers a population of 2760 citizens living in the Municipality of Danilovgrad, aged between 50-74 years, with an average risk of colon cancer, without a positive history of polyps and/or colorectal cancer and no history of arthritis intestine (Ulcerative colitis, Crohn's disease).

Calls for screening for early detection of colorectal cancer defined by this project are sent to the home addresses of persons aged between 50-74 years, based on updated lists of the Ministry of Interior of Montenegro and the database of the Health Care Center Danilovgrad. With an invitation letter, the examinees receive tests and the instructions on the implementation of the test, corresponding questionnaire, flyer and educational brochure about the early detection of colorectal cancer, which was prepared by the Health Care Center Danilovgrad.

All persons fill out the questionnaire that except for personal data on the person, contains information about the possible causes for the development of colorectal cancer: diet, lifestyle and habits (physical activity, smoking, alcohol), previous diseases of the colon (inflammatory bowel disease, polyps, cancer), and family anamnesis. The examinees are sent to their home address test on occult blood in the stool, instructions on how to implement the test as well as instructions on the preparation procedures before taking the test.

In case of the positive tests the Health Care Center with the chosen doctor, delivers positive

tests on occult blood to home address, with an invitation to contact the chosen doctor for referral to colonoscopy, in order to find the cause of bleeding and possibly remove the risk of colon polyps, and so prevent the occurrence of colorectal cancer or detect the colon cancer at an early stage of growth.

The implementation of this program includes in addition to the Health Care Center, chosen doctors, nurses, visiting nurses, biochemists and technicians in the biochemical laboratory of the Health Care Center, subspecialists gastroenterologists and abdominal surgeons from the Clinical Center of Montenegro.

This project, according to successful evaluation results that were presented in January 2011, represents a good basis for the creation of the Strategy for the implementation of early detection of colorectal cancer at the national level, which is in accordance with the Article 33 of the Law on Health Insurance.

## IV Regional overview

### 4.1 Serbia

#### *Current situation in Serbia*

According to the latest census from 2002, Serbia (without Kosovo) has an estimated population of 7.5m (5.466.000 in Central Serbia and 2.032.000 in Vojvodina). Compared to the 1991 census, the population was reduced by 4.4%. Furthermore, 30.000 people die of cancer in Serbia every year according to the Central Serbia Cancer Registry and Registry for malignant neoplasms of Vojvodina.

<sup>42</sup>

According to the data for Serbian Registry of cancer, cardiovascular diseases and malignant tumors make over two thirds of deaths in 2009 in Serbia. More than half of all deaths (54.8%) are caused by blood vessel diseases, while every fifth of the death is caused by malignant tumors. From 2002 to 2009 there was an increase of 3.6% in overall death rate in Serbia, closely connected to the frequency of deaths caused by leading noncommunicable diseases. The biggest increase in death rates happened in the cases of obstructive pulmonary diseases (26.3%), diabetes (23.2%), and malignant tumors (16.1%), whereas the death rates in the cases of heart and blood vessel related diseases were the least (2.8%).<sup>43</sup>

Epidemiological situation of malignant tumors was until recently analyzed based on the death rate data, despite the fact that the Registry was established in 1970. The primary role of this Registry is to provide accurate count of all new cases of cancer, correct classification and coding, so as the data on cancer related deaths. Additionally, the Registry must have correct evaluation of the population under risk, in relation to the years of age and gender. However, wrong management, insufficient education of health workers so as the lack of IT support resulted in sub-registration of new new-found cases of cancer so as the low quality of data at the initial registration. In the period 1986-1995 the number to patients suffering from malignant tumors that were registered in the Registry was approximately the same of even lower than that of the number of patients died of cancer. That was the reason why the reorganization of Registry for Cancer was initiated. In the period 1996-2006, the Registry noted an

<sup>42</sup> National guidelines for primary care doctors, Prevention of malignant diseases, Ministry of Health, Serbia, November 2005

<sup>43</sup> Health statistics of Republic of Serbia, 2009, Institute for Public Health, Belgrade 2010. ISSN 2217-3714



increase in the rate of diseases.<sup>44</sup>

In the year 2000<sup>45</sup> colon and rectum cancer was 5th on the list of causes of death accounting for 2.7 %. Every year approximately 3800 cases of malignant colon tumors are registered while 2300 people dies of this type of cancer yearly. These numbers represent the second most commonly discovered cancerous disease in Serbia. In the year 2006<sup>46</sup>, colon and rectum cancer counted for the 11.9% of most common mortality causes after the lung cancer in men and breast cancer for women.

In the territory of Central Serbia for the period 2002-2007, 24.493 people were diseased from malignant neoplasms, while 13.791 persons died. According to the data from the Registry of Cancer in Central Serbia, 25.662 persons were diseased in 2007, while 14.373 died. The incidence of this disease was 532.2 persons per 100.000. In the case of mortality caused by cancer, recorded death rate was 271.4 per 100.000 people, while the rate was 292.5 in the year 2009.<sup>47</sup> According to the data of the cancer registry, the mortality in men was most present in the cases of bronchial and lung cancer, prostate cancer, colon and rectum cancer. In women, malignant tumor was most commonly localized in breast, cervix, colon and rectum.

Comparing to the nationals of other European countries, citizens of Republic of Serbia are in the medium rise for developing the disease and death caused by malignant diseases excluding lung and cervix cancer in which cases Serbia is one of the leading countries in Europe.<sup>48</sup>

#### ***4.1.1 Normative framework regulating the malignant neoplasm in Serbia***

The laws regulating the area of malignant diseases in Serbia are the Law on healthcare and Law on health insurance, which can be considered as general legislative acts regulating this area. Apart from these, there are also laws regulating the prevention, control and treatment of malignant diseases, such as the Law on data collections in the field of healthcare. Within the governmental framework for the development of health care, the Ministry of Health implements strategies important for prevention of malignant diseases: Strategy for prevention and control of chronic noncommunicable diseases<sup>49</sup> and the Poverty alleviation Strategy.<sup>50</sup>

Serbian Government adopted the Poverty alleviation Strategy in 2003, which deals with poverty as a multidimensional phenomenon. As such, poverty not only includes satisfaction of basic human needs, but also includes unemployment, accommodation and inadequate approach to social protection, health, educational and communal services. Related to the health care, the Strategy predicts better distribution of resources in order for preventive and primary health care to have high priority in the system of health protection. Additionally, the reform regulates financing of public health institutions, with the aim of providing prevention and early detection of diseases, especially for malignant and cardiovascular diseases.<sup>51</sup> The primary goal is improvement of public health, decrease in inequalities in health, which is to be achieved through the improvement of status of vulnerable groups, including

44 Cancer Registry, Institute for public health of Serbia, October 2006

45 National guidelines for primary care doctors, Prevention of malignant diseases, Ministry of Health, Serbia, November 2005

46 National Program for fight against cancer, Ministry of Health of Republic of Serbia

47 Health statistics of Serbia, Institute for Public Health of Serbia, ISSN 2217 - 3714

48 National program for the prevention of colorectal cancer, Ministry of Health of Republic of Serbia

49 Strategy for the prevention and control of chronic noncommunicable diseases of Republic of Serbia

50 Strategy for the poverty alleviation in Serbia, Belgrade 2003

Ibid.

51 Ibid.

the diseased from malignant neoplasms.

Apart from the aforementioned strategies, the Ministry of Health is implementing national programs and guidelines for prevention of malignant diseases, colon cancer in particular, such as the National program for cancer prevention<sup>52</sup>, the National program for prevention of colorectal cancer<sup>53</sup>, the National guide for primary healthcare doctors<sup>54</sup> and the National Guide for clinical practices.<sup>55</sup>

Paragraph 1, Article 11 of the **Law on healthcare**<sup>56</sup> stipulates that “social care for health, under equal conditions, in the territory of Republic of Serbia is achieved through providing health protection to those groups that are exposed to the increased risk of infection, health protection in relation to prevention, early detection and treatment of the diseases of wider social-medical importance, as well as the health protection of socially vulnerable population.” Healthcare of population affected by malignant diseases is regulated by the same Article, paragraph 2, point 5. Also, article 18, paragraph 5 stipulates that it is in the public interest of the Republic of Serbia to implement monitoring and prevention of chronic noncommunicable diseases, including malignant neoplasms. This is achieved on the primary level of healthcare, regulated by the Article 88, paragraph 1, and point 4 of the Law on healthcare. Main principles of this law provides for integrated healthcare and prevention of both communicable and noncommunicable chronic diseases at the national level. The principles are:

- Availability of healthcare,
- Equity in healthcare,
- Health care comprehensiveness
- Health care continuity
- Health care quality improvement
- Health care efficiency.

The Law on Healthcare further provides that the National Assembly shall adopt the Plan of development of health care (Article 16, paragraph 1). The development plan is based on the analysis of population health, the population needs for healthcare, and available human, financial and other capacities (Article 17, paragraph 1). One of the main objectives of the Plan of development of healthcare of Serbia 2010 – 2015<sup>57</sup>, is to reduce morbidity and premature mortality from malignant disease. Following activities are being implemented:

- Implementation, monitoring and evaluation of National Program “Serbian against cancer”;
- Implementation, monitoring and evaluation of National Program for prevention of breast cancer;
- Implementation, monitoring and evaluation of National Program for Prevention of Cervical Cancer;
- Implementation, monitoring and evaluation of National Program for Prevention of colorectal cancer

Article 16, paragraph 2 of the Law on healthcare stipulates that the Government adopts relevant programs with the aim of implementing the Plan of development of healthcare. Some of the programs that the Government adopted in relation to the prevention, early detection and control of malignant diseases are: National program for the prevention of cancer, National program for the prevention of

52 National program for cancer prevention, Ministry of Health of Republic of Serbia

53 National program for the prevention of colorectal cancer, Ministry of Health of Republic of Serbia

54 National guide for primary healthcare doctors, Prevention of malignant diseases, Ministry of Health of Serbia, November 2005

55 National guide for clinical practice, Minimal clinical recommendations for diagnosis, treatment and monitoring, Ministry of Health of Serbia, September 2002

56 The Law on healthcare, Government of Serbia, “Official Gazette of Serbia“, numbers 107/05 and 72/09

57 Plan of development of healthcare in Serbia 2010-2015, Ministry of health of Serbia

colorectal cancer, National program “Serbia against cancer” and National program for testing the colon cancer.<sup>58</sup>

Article 22, paragraph 1 of the **Law on health insurance** stipulates that the beneficiaries of mandatory health insurance are: persons who belong to groups that are exposed to increased risks of developing the disease, persons who need healthcare in relation to the prevention, early detection and treatment of diseases of broader socio-medical significance, as well as socially vulnerable persons. Point 5 of the same article includes persons diseased from malignant neoplasms.

## 4.2. Croatia

### *Current situation of malignant diseases in Croatia*

Cancer is an important health issue for the citizens of Croatia. It represents the second most important cause of death, right after cardio-vascular disease; therefore it is very important to assess the actual data which would help devise a strategy for prevention and protection. Only a well-organized registration of cancer can ensure assessing that data. Consequently, the incidence and mortality rates from cancer in Croatia are monitored and studied by the State Registry for cancer, a population registry established within the Croatian Institute for Public Health. Registry for Cancer of Croatia was founded in 1959. Starting from 1968, the data are being processed electronically. From 1994, the Registry is a full member of the International Association of Registries for Cancer in Lyon, France. By participating in the European Network of Cancer Registries (ENCR), the Registry became an integral part of the incidence and mortality from cancer database (EUROCIM).

The first cause of death in Republic Croatia in 2009 were cardio-vascular diseases, with fatal outcome for 25.976 persons or 586.5/100000 citizens. From malignant neoplasm, the second group of diseases which are the leading causes of death, 13 496 people passed away, or 304.7/100 000 citizens. Three quarters of all causes of death in Croatia belongs to these two groups, while the rest of the causes are related to injuries and poisoning, gastrointestinal problems, lung diseases and other less prevalent causes.<sup>59</sup>

According to the data of the Cancer Registry of the Croatian Institute for Public Health, intestinal cancer is a second most frequent form of cancer among men (after the lung cancer) and women (after the breast cancer) which overall represents 15% of men and 13% of women. In the period from 1983 to 2004 the number of new cases of intestinal cancer increased from 1 186 to 2 653 (124%), and the number of deceased increased from 840 to 1 564 (86%). From recently discovered 2653 patients throughout 2004, 1 531 are men and 1 122 are women. The main reason for a continuous rise in mortality is the condition of the intestinal cancer at the moment of diagnosis – only less than 10% of all the carcinoma was localized on the intestinal wall. For the last few years a more adequate treatment of this disease can be noted, since there was an increase in the five-year survival of gastrointestinal cancer from 35% to 39% for men and from 35% to 42% for women.<sup>60</sup>

58 National Program for testing the colon cancer – Informative brochure, ISBN: 1-74186-606-5, ISBN: 1-74186-607-3, Number of publication: P3 - 386

59 The report about deceased people in Croatia in 2009 , [http://www.hzjz.hr/publikacije/umrli\\_2009.pdf](http://www.hzjz.hr/publikacije/umrli_2009.pdf)

60 Cancer Registry of Republic Croatia [http://www.hzjz.hr/rak\\_index.htm](http://www.hzjz.hr/rak_index.htm)

#### 4.2.1 Legal Acts which regulate malignant neoplasm in Croatia

The laws which regulate prevention and control of malignant neoplasm in Croatia are the Law on Public Protection<sup>61</sup>, the Law on mandatory health insurance<sup>62</sup>, the Law on protection of the rights of patients<sup>63</sup> as well as numerous national strategies and programs conducted by the Ministry of Health and Social care.

**National strategy of health development 2006-2011**<sup>64</sup>, brought by the Croatian Sabor on July 9th 2006, envisions that a decrease in mortality caused by malignant diseases can be achieved by early tumor discovery programs like

- Program for early breast cancer discovery in 2006
- Program for early intestinal cancer discovery in 2007
- Program of early ovarian cancer discovery in 2009
- Program of early prostate cancer discovery in 2009

All these programs are already under way in Croatia.

**As a part of the Strategic plan from 2010–2013**<sup>65</sup>, conducted by the Ministry of Health and Social Care believes that in the interest of protection and development of health it is essential to promote healthy lifestyles which will make an impact on the quality and longevity of life, a decrease in chronic non-contagious diseases as well as some malignant diseases. The Ministry of Health and Social Care will continue with previously started programs of early breast cancer and intestinal cancer discovery and begin with new programs for discovering cancer. As one of the benchmarks of the Plan success are early discovered carcinoma and for ensuring an implementation of this type of protection of the public health interests, an increase in the outcome of gastrointestinal bleeding testing was planned, which would represent a continuation of the previously activated programs regarding the early cancer development and newly founded malignant diseases monitoring.

The Ministry for Health and Social Care of Croatia also conducts the **National program of early intestinal cancer development**<sup>66</sup>. This program makes a significant contribution to the improvement of the population health because **by preventive measures malignant intestinal tumors are discovered in their early stadiums, in the stadium of premalignant lesions or early carcinoma, when the probability for a successful treatment is large.** This program should include the whole targeted population and all the citizens need to have an equal opportunity to participate in the program, including the socially endangered ones. The goals of the Program are:

- To decrease the mortality from intestinal cancer at least for 15% in the next five years after the program has been conducted
- To test at least the 60% of the invited people
- To discover cancer in its early stadiums and therefore enhance the possibility of curing the diseased and improving their lifestyle
- To analyze 75% of the risky groups in the population with early cancer discovery by 2015

This Program has also presented **preventive measures and early intestinal cancer discovery. Those**

61 Law on public protection, Croatian Sabor, Zagreb, January 15th, Class 500-01/08-01/03

62 Law on mandatory health insurance, Zagreb, January 15th, Class 500-01/08-01/12

63 The law on the protection of the rights of patients, Zagreb, December 24, 2004, Number: 01-081-04-3610/2

64 National strategy of health development 2006-2011, Croatian Sabor, 2006

65 Strategic plan 2010 – 2013, Ministry of Health and Social Care of Croatia

66 Program for early intestinal cancer development, Ministry for Health and Social Insurance of Croatia, Zagreb, 2007

**are mostly tests of occult fecal bleeding, proctosigmoidoscopic test and colonoscopy with twofold contrast as well as determination of tumorous markers.** The whole process begins with a media campaign about the prevention and early intestinal cancer development and encouraging people older than 50 to get tested. The call for testing is sent to the home addresses of the persons between 50 and 74 based on the census. Along with the invitation, a brochure explaining the Program, a survey to determine if that person is a potential member of the risk group and potential risk factors for the start of the disease are sent. The invitation also contains the manual for the performing of the test and three more test on a presence of occult blood in stool. The testing is conducted at home and it is delivered for results after one or two days to the Institute for Public Health of Zagreb, after which the Institute arranges a check for the individuals with positive test results and delivers a call for colonoscopy and guidelines for preparation to the home address. The results of testing, survey papers as well as suitable diagnostic findings are collected and analyzed by local institutes for public health, and the monitoring and evaluation are conducted by the Croatian Institute for Public Health.

### 4.3 Bosnia and Herzegovina

#### *Current situation of malignant diseases in Bosnia and Herzegovina*

The health condition of Bosnia and Herzegovina Federation citizens is characterized by important demographic changes, significant presence of chronic diseases and a high prevalence of unhealthy life habits<sup>67</sup>. With already prevalent health issues, new ones are occurring, which deteriorates the health of Bosnia and Herzegovina citizens. Negative health indicators like mortality and morbidity are used in order to rate the health condition of the citizens, as well as other indicators of the recent research.

In 2007, mortality rate had a mean of 8.3‰ and displays a slow but continuous growth as a reflection of the aging of the citizens. The lead causes of death in 2007 are circulatory system diseases (54.3%), with the second cause being malignant neoplasm with 19.1%, which means that almost three quarters of all the causes of death are in these two groups. The diseases of endocrine system and metabolism with eating disorders are also highly ranked with 4.0%. A direct consequence of the negative prevalence of the risk factor is noted, as well as an increase in the chronic diseases among the population. Comparing standardized mortality rates from malignant neoplasm with the countries in the region, Bosnia and Herzegovina has a low death rate of 137.9/100 000 citizens, as opposed to Croatia whose malignant neoplasm mortality rate is 210.24/100 000 citizens.

Five leading causes of death from malignant neoplasm in Bosnia and Herzegovina in 2007 were malignant neoplasm of bronchi and lungs with 26.3 %, then malignant neoplasm of liver and intrahepatic gallbladder (7.4%), followed by gastritis malignant neoplasm. Among men, who die more frequently from malignant neoplasm than women, the lead causes of death are malignant neoplasm of bronchi and lungs with 36.2%, followed by gastrointestinal and prostate malignant neoplasm. Among women, the lead cause of death from malignant neoplasm is malignant neoplasm of breast (14%). Malignant neoplasm of bronchi and lungs are also highly ranked (12.2%)<sup>68</sup>

Because of the significance of malignant neoplasm in morbidity and mortality in Bosnia and Herzegovina, a population registry has been established. The first results of the population registry of malignant diseases in Bosnia and Herzegovina for the year 2005 “CanReg4” showed that the overall rate in 2005 was 170,18/100 000 citizens. Intestinal cancer is one of the most frequent forms

<sup>67</sup> The report about deceased people in Croatia in 2009 , [http://www.hzjz.hr/publikacije/umrli\\_2009.pdf](http://www.hzjz.hr/publikacije/umrli_2009.pdf)

<sup>68</sup> Cancer Registry of Republic Croatia [http://www.hzjz.hr/rak\\_index.htm](http://www.hzjz.hr/rak_index.htm)



of carcinoma, which equally attacks both genders in this country with a high death rate. **Also, by introducing the register it has been noticed that the frequency of intestinal carcinoma has been continuously and significantly increasing and that there are indications that this type of cancer will soon become the most frequent form of carcinoma in Bosnia and Herzegovina.** According to the International agency for cancer investigation from Lyon, 663 newly founded diseased from colorectal carcinoma among the female population is expected, with 826 diseased among the male population. 836 deaths, caused by this disease, are expected yearly.<sup>69</sup>

#### *4.3.1 Legal acts that regulate malignant neoplasm in Bosnia and Herzegovina*

The Federation of Bosnia and Herzegovina bases its laws in the area of health on international conventions, declarations and treaties. Two essential laws that are regulating this area are the Law on health insurance and the Law on health protection.<sup>70</sup> In the article 8, Law on the health protection, it is stated that the Federation of Bosnia and Herzegovina, as a part of activities designated from the field of health protection, is obliged to ensure malignant diseases prevention, and based on the article 16, point 5, it is obliged to enforce measures and activities for prevention, early discovery and moderation of contagious, chronic, mass non-contagious and malignant diseases. Law on health insurance<sup>71</sup>, article 32, states that health protection entails treatment of malignant diseases. The Law on rights, obligations and responsibilities of the patients<sup>72</sup> and the Law on records in the area of health<sup>73</sup> also entails the area of prevention, treatment and control of malignant diseases. Apart from the law, the Government of the Federation and the Ministry of Health are bringing strategies and programs important for prevention and control of malignant diseases. Some of them are: Strategy for development of primary health protection<sup>74</sup>, Strategic plan of health development in Bosnia and Herzegovina Federation in the period from 2008 to 2018<sup>75</sup> and the Program for prevention and early discovery of intestinal cancer.

The government of federation of Bosnia and Herzegovina brought the *Program for prevention and early discovery of intestinal carcinoma, through which was also brought the Guide for prevention and early discovery of intestinal carcinoma*<sup>76</sup>, which goal is to point out the possibility of efficacious and safe method of prevention and early discovery of the intestinal cancer in the easiest way. The goals of using the Guide are:

- To lower the frequency of intestinal cancer by designated preventive methods, especially by giving advice on diet and healthy lifestyle
- Premalignant lesions can be diagnosed and removed with frequent and proper screening, thereby lowering the frequency of the intestinal cancer
- By conducting screenings, malignant diseases can be revealed in an early stage, which ensures an improvement of colorectal carcinoma treatment

69 Law on public protection, Croatian Sabor, Zagreb, January 15th, Class 500-01/08-01/03

70 Law on mandatory health insurance, Zagreb, January 15th, Class 500-01/08-01/12

71 The law on the protection of the rights of patients, Zagreb, December 24, 2004, Number: 01-081-04-3610/2

72 National strategy of health development 2006-2011, Croatian Sabor, 2006

73 Law on record in the area of Health "Official Gazette of Bosnia and Herzegovina" no. 2/92 and 13/94

74 Strategy for the development of primary health protection, Federal Ministry of health, Federation of Bosnia and Herzegovina

75 Strategic plan of health development in Federation of Bosnia and Herzegovina in the period from 2008 to 2018, Federal Ministry of Health, Federation of Bosnia and Herzegovina

76 Guide for prevention and early discovery of gastrointestinal carcinoma ISBN 978-9958-695-15-5 (Ministry of Health KS)

The methods of early intestinal cancer discovery which are envisaged by the Guide are: **stool testing on occult bleeding, colonoscopy, digital rectal check as well as carcino-embryonic antigen (CEA)**. It is estimated that the testing would decrease the mortality caused by colorectal carcinoma if the person, age 50 to 80, would undergo it at least once a year or once in two years on the samples of diluted or undiluted stool. **The possibility of monitoring high-risk patients for colorectal carcinoma increased the discovery of neoplasm in the early operable stage of the disease.**

With regards to the probability of intestinal carcinoma, the population is divided into three risk groups. In the first group are the people with a **high risk** that have **intestinal diseases, inherited polyposis, early colorectal carcinoma, early adenoma polyp or symptoms and signs that incite suspicion on the intestinal tumor**. In the other group, with a more moderate risk, are people older than 45 without symptoms or signs that incite suspicion on the intestinal tumor, while in the last group are people with a low level of risk, asymptomatic persons younger than 45. To the asymptomatic persons and persons with a moderate risk, testing on the occult bleeding is suggested at least once a year, starting from the age of 45. They are also suggested to start colonoscopy from 45, so if the two checks in the two years are negative, the checks should be continued every 3-5 years. Yearly testing on the occult blood is recommended to the people with a higher risk, colonoscopy to the persons who previously suffered a colorectal carcinoma and early adenoma polyp, while the persons with inherited polyposis is suggested to start screening in their 14th year, including the family.

## V Conclusion and recommendations

### *Proposed measures for implementation of the prevention and early detection of colorectal cancer in Montenegro*

The issue of prevention and early detection of colorectal cancer in Montenegro is legally established, while there are no mechanisms necessary for the proper implementation. The lack of the Registry substantially prevents the monitoring and implementation of planned activities, which further complicates planning and systematization of health care. The preparation of national clinical practice guidelines on prevention, diagnosis and treatment of colorectal cancer is a prerequisite for the preparation of the National program of prevention and early detection of colorectal cancer. Early detection of colorectal cancer should be provided through the implementation of preventive examinations, as well as development of screening modalities for categories of patients at average and increased risk of developing the disease. Categorization of patients in terms of the risks for developing the disease, it is necessary to prepare and distribute brochures and questionnaires at the National level, and update the Registry with obtained data. Finally, introduction of molecular analysis for determining the genetic load for some hereditary factors that lead to the development of this disease, would significantly contribute to reducing the medical costs.

#### **5.1 Legal regulation of early detection of colorectal cancer at the primary health care level**

Article 33 of the Law on Health Care Law defines health services that are implemented at the primary health care level, which include detection, prevention and control of malignant diseases. The Law on Health Insurance further defines medical measures and procedures for prevention, suppression and early detection of malignant diseases (Article 17). Finally, the article 12 of the Regulation on the

extent of rights and standards of health care and mandatory health insurance regulates the preventive screenings of cervical and breast cancers. Consequently, preventive screenings for early discovery of colorectal cancer at the primary health care level are not implemented, even though such obligation is legally established.

**Problem:** Failure to meet legal obligations defined by the Article 33 of the Law on Health Care and Article 17 of the Law on Health Insurance.

**The consequence:** The lack of implementation of early detection of colorectal cancer at the level of primary health care.

**Objective:** The establishment or amendments of a legislative framework for the early detection of colorectal cancer at the level of primary health care.

**Measures:**

1. Adoption of regulation in accordance with the Article 33 of the Law on Health Care, which would regulate preventive examinations in terms of early detection of colorectal cancer at the primary health care level.

2. Amendment of the Article 12 of the Regulation on the extent of rights and standards of health care and mandatory health insurance, which would include preventive screening tests for colorectal cancer.

### **5.2 Registry for colorectal cancer**

**Problem:** Failure to fulfill legal obligation of establishing the Registry of malignant neoplasms in Montenegro.

**The consequence:** Difficulty for systematization of prevention and early detection of colorectal cancer

**Objective:** Establishment of the National Registry for malignant diseases, which would include information on colorectal cancer and establishment of a Registry for hereditary tumor syndromes.

**Measures:**

3. Implementation of the legal obligations defined by Articles 2, 8 and 9 of the Law on data collections in the field of health, in terms of preparing the National Registry for malignant neoplasms, including colorectal carcinoma.

4. Implementation of the legal obligations defined by Articles 2, 8 and 9 of the Law on data collections in the field of health, in terms of preparing the Registry for hereditary tumor syndromes.

### **5.3 National clinical practice guidelines for the prevention and diagnosis of colorectal cancer in Montenegro**

**Problem:** Lack of national clinical practice guidelines for the prevention and diagnosis of colorectal carcinoma.



**The consequence:** Lack of clearly defined clinical recommendations for the prevention and diagnosis of colorectal carcinoma.

**Objective:** Preparation of national guidelines that would define the procedures on prevention of colorectal cancer.

**Measure:**

5. Improvement of the existing health system in Montenegro, through preparation of national clinical practice guidelines on the prevention and diagnosis of colorectal cancer, by eminent experts in this field, which would be in accordance with European recommendations

**5.4 Screening tests for persons at average risk of developing colorectal cancer at the primary health care level**

**Problem:** Lack of preventive examinations in primary health care for persons with average risk of developing colorectal cancer

**The consequence:** Failure to achieve early detection of colorectal cancer for patients without symptoms and risk factors, resulting in late detection of colorectal cancer.

**Objective:** Implementation of preventive examinations in primary health care for persons with average risk for developing colorectal cancer, with the aim of detecting bowel polyps and colorectal cancer in early stages.

**Measures:**

6. The implementation of screening modalities for persons at average risk for developing this disease, through fecal occult blood testing. The target population includes males and females aged between 50-74, without personal anamnesis of polyps and/or colorectal cancer, no anamnesis of inflammatory bowel disease and no family anamnesis of colon cancer.

7. Preparation and distribution of flyers and brochures on early detection of colorectal cancer, at the national level

8. Preparation and invitations for occult blood testing

9. Preparation and distribution of questionnaires on the existence of risk factors for colorectal cancer

10. Supply and distribution of tests for occult blood in the stool to home addresses

11. Processing of the questionnaires and updating of the Registry for colorectal cancer

**5.5 Center for the implementation of molecular analysis on the presence of gene load/inherited syndromes that lead to the development of colorectal cancer**

**Problem:** The lack of molecular analysis that helps determine gene load/hereditary syndromes, which lead to the development of colorectal cancer

**The consequence:** Referral of patients abroad to perform molecular analysis and significantly increased cost of diagnosis

**Objective:** Implementation of molecular analysis on hereditary tumor syndromes that lead to the development of colorectal cancer.

**Measures:**

12. Expanding the activities of the Center for Genetics of the Clinical Center of Montenegro, so that it includes genetic analysis of hereditary non-polyposis colorectal cancer, familial adenomatous polyposis, Peutz-Jeghers syndrome and juvenile polyposis.

**5.6 Screening tests for persons at an increased risk of developing colorectal cancer at the primary health care level**

**Problem:** Lack of preventive examinations in primary health care for persons with an increased risk of developing colorectal cancer

**The consequence:** Failure to achieve early detection of colorectal cancer for patients with an increased risk for developing colorectal cancer

**Objective:** Implementation of preventive examinations in primary health care for persons with an increased risk for developing colorectal cancer, with the aim of polyposis and colorectal cancer in the early stages, when complete healing is possible.

**Measures:**

13. The introduction of criteria for the classification of persons with increased risk of suffering from KRK

14. Production and distribution of flyers and brochures on early detection of colon cancer

15. Creating and sending a questionnaire about possible risk factors for developing colon cancer, which include providing information on the existence of a positive family burden of colorectal cancer, and genetic load of pre-cancerous diseases.

16. Updating the Register for colorectal cancer and hereditary Registry tumor syndromes data collected questionnaires

17. Referral of patients by doctors selected in the third level institution to perform molecular analysis of belonging to one of the above syndrome, and then possibly to colonoscopy according to established criteria.

13. The introduction of criteria for the classification of persons with an increased risk for the development of colorectal cancer

14. Preparation and distribution of flyers and brochures on early detection of colorectal cancer

15. Preparation and distribution of questionnaires about possible risk factors for the development of colorectal cancer, which would include information on the existence of a positive family burden of

colorectal cancer and genetic load of pre-cancerous diseases.

16. Update of the Registry for colorectal cancer and the Registry for hereditary tumor syndromes based on the data collected from questionnaires.

17. Referral of patients by chosen doctors to the third level institutions to perform molecular analysis with the aim of determining the presence of syndromes, or colonoscopy.

### **5.7 Education and training of gastroenterologists for performing the colonoscopy**

In Montenegro, there are not enough gastroenterologists appropriately trained to perform colonoscopy, which is one of the prerequisites for successful screening. Education of doctors is one solution to this problem.

**Problem:** Lack of adequately trained subspecialist gastroenterologists to perform endoscopic procedures.

**The consequence:** Percentage of achieved total colonoscopies is below international standards

**Objective:** Implementation of adequate, total colonoscopies

**Measure:**

18. Education of medical personnel and training of gastroenterologists in the renowned endoscopic centers in the region, as well as in the EU countries.



## About organisations

**Coalition for Social Changes** was established on the 15th of December 2009, among ten leading organizations of civil society in the area of health, social protection, labor market and education: The Monitoring Center, AD Center Equista, Center for Civic Education, Juventas, CAZAS, Institute for Social inclusion, Pedagogical Center of Montenegro, Montenegrin Association of Youth with Disabilities, Association of parents of Children with Disabilities „Sunbeam“. The Coalition is open for who all interested organizations of civil society, dealing with problems of poverty and social exclusion, can freely join. Main aim of forming of the Coalition is contribution to strengthening of advocacy capacities and watchdog functions of civil society organizations in Montenegro, in order to influence creation of policies and laws in the area of education, labor market, social and children's protection.

### *Juventas*

Juventas is a non-profit organization established on January 29th, 1996 in Podgorica. Juventas envisages Montenegro as a stable, democratic society in which young people can freely express utilize their potential. Some of the goals of Juventas are: to stimulate critical thinking and develop a culture of dialogue, promotion of culture, peace, tolerance and peaceful conflict resolution, promotion of human rights, healthy lifestyles, and fight against drug abuse. More information at [www.juventas.co.me](http://www.juventas.co.me)

### *The Monitoring Center – CEMI*

The Monitoring Center – CEMI is a nongovernmental, non-profitable organization founded in May 2000, whose main goal is to provide infrastructural and expert support for continuous monitoring of the process of transition in Montenegro. CEMI envisages Montenegro as a land of free citizens, the rule of law, social justice and equal opportunities. The mission of CEMI is to continuously provide support to reforms and strengthening of institutions of political system and civil society organizations, by proposing and monitoring the implementation of public policies in the fields of human rights and freedoms, fight against corruption and Euro-Atlantic integration of Montenegro. CEMI implements its activities through three programs: Democratization and human rights, Fight against corruption and European Integration, while the organizational structure consists of four departments: Public policy research department, Legal department, Public opinion survey department and Public Relations Department. More information at: [www.cemi.org.me](http://www.cemi.org.me)

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### *Mensur Bajramspahić, Public policy researcher*

Born in Bijelo Polje, on 29.04.1986, where he graduated with honors from elementary school, elementary music school and high school. He graduated from the American University in Bulgaria, with a major in Political Science and International Relations and two minors: Literature and Fine Arts. He studied at the University of North Carolina, Asheville, through International Student Exchange Program.

During his study, he was a member of the Debate club, University Choir, Better Community club. With the camp “Hope”, he participated in the reconstruction of New Orleans.

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