

BRIEF SYNTHESIS OF THE COUNTRY REPORT IN BULGARIA

Report created in the framework of the project Promoters of advanced oncogenetics open online training and multimedia raise awareness on multidisciplinary assessment of patients and their families at risk of hereditary or familial cancer, Reference number 2018-1-RO01-KA202-049189, Strategic Partnerships for vocational education and training Erasmus+ programme

1. Current epidemiological situation of cancer, and of hereditary cancer in particular (breast, ovarian, colorectal and other types) in Bulgaria.

As of 31 December 2015 the Bulgarian population is 7 153 784 persons representing 1.4% of the population of the European Union. Life expectancy in the country, calculated for the period 2013 – 2015 is 74.5 years.

1.1. Incidence

The data used in this report are taken from the Bulgarian National Cancer Registry (BNCR) /www.sbaloncology.bg/. Cancer registration has been compulsory in Bulgaria since 1952.

According to BNCR data for cancer incidence in Bulgaria in 2015, the number of new cancer cases were 35265 and the crude incidence rate was 491.3 per 100 000 inhabitants. In men the prevalence was higher - 530/100 000, whereas in women it was 454.7/100 000 inhabitants.

A statistically significant increase is observed in the number of new cancer cases for all types. Over the past 20 years, the number of newly registered cancer cases has risen by an average of 678.81 cases per year. Disturbing is the fact that a great part of the newly diagnosed cases were in an advanced stage.

The newly diagnosed cases in females were as follows: for breast cancer 3988, with a crude incidence rate of 108.1 per 100 000; for ovarian cancer - 825 new cases, with a crude incidence rate of 22.4/100000. Breast cancer is the most common malignant disease among women. It represents 26.8 % of all malignant diseases in females. Colon cancer comes third in incidence (8.1%), ovarian cancer is fifth (5.5%). Colon cancer is third in incidence in males as well (9.5%). In colon cancer the crude incidence rate in males was higher as compared to that



of females - 1541 cases, or 44.2/100 000 vs 1202 cases, or 32.6/100 000, respectively. The total crude incidence rate for colon cancer in Bulgaria was 38.2/100 000 for year 2015.

1.2. Prevalence

The number of cancer patients (all sites) registered in Bulgaria was 284 355 by 2015, which represented a crude prevalence rate of 3961.5 per 100 000, i.e. 4% - 4 people out of every 100 were diagnosed with cancer. In females the crude prevalence rate was higher as compared to males - 170 860 and 113 495 cases, respectively, or 4632.4 /100 000 vs 3252.4/100 000.

The number of colon cancer patients registered in Bulgaria was 18647 by 2015, which represented a crude prevalence rate of 259.8 per 100 000. In males the crude prevalence rate was higher as compared to females - 265/100 000 vs 254.8/100 000. In females the crude breast cancer prevalence rate was 1385.6/100 000 and the crude ovarian cancer prevalence rate was 202.4 per 100 000.

1.3. Mortality

BNCR data show that the number of cancer deaths in 2015 was 17932, which represented a crude mortality rate of 249.8/100 000 people. In men this index was higher - 10412 cases, or 298.4/100000, as compared to that of women – 7520 cases, or 203.9/ 100 000. Mortality due to colon cancer was higher in males – 954 cases, 27.3/ 100 000 as compared to females – 738 cases, 20/100 000 inhabitants. A considerably higher mortality rate was observed in breast cancer of women - 1312 cases, or 35.6/100 000. Mortality due to ovarian cancer was lower - 438 cases, or 11.9/100 000 .

2. Current situation of the National Strategies in models of genetic risk assessment for hereditary cancer (HBOC, CRC and other types) in Bulgaria

At present there are no National Strategies for genetic tests and risk assessment for hereditary cancer (HBOC, CRC and other types) in Bulgaria.



3. Current practical situation in Genetic Testing Availability for HBOC and CRC in Bulgaria.

Currently, genetic tests for hereditary colon cancer, ovarian cancer and breast cancer in Bulgaria are provided by a number of private laboratories and commercial intermediaries. Most of these tests are performed abroad and the time needed to obtain results varies from weeks to months. The setback is that not all patients receive genetic counseling from a specialist in medical genetics when they get their results.

4. The situation of the current Research Programs on mutation screening and founder mutation detection for HBOC and CRC in Bulgaria.

At present, studies on hereditary colon cancer, ovarian cancer and breast cancer in Bulgaria are performed at the Center for Molecular Medicine, Sofia.

Currently the Department of Medical Genetics in Plovdiv carries out activities within the framework of Project No BG05M2OP001-1.002-0005-C 01 Center for Competence "Personalized Innovative Medicine (PERIMED)". The project is in the field of oncology, genetics, personalized medicine and pharmacogenetics. The project will contribute to providing an earlier and more accurate diagnosis of cancer by minimal invasive approaches, will lead to accurate personalized therapy and prognosis, and monitoring for minimal residual disease for each individual patient. This project will contribute to the precise choice and dosing of the therapeutic agents used in each individual patient. Additionally, the frequency and type of the polymorphisms studied will be determined for the Bulgarian population. The study of minimal residual disease using droplet digital PCR as a criterion for the effect of treatment in cancer patients is extremely important in view of the current trends in predicting the individual risk of relapse, as well as in limiting the toxic effects of chemotherapy.

5. List of institutions, cancer centers, etc. that provide genetic testing and counseling services in Bulgaria

Genetic laboratories in Bulgaria, as well as other laboratories, are two types: located in hospitals or acting as outpatient care facilities. The latter are mainly private genetic laboratories. The Genetic Laboratories, which are located in the University Hospitals in Varna, Pleven, Stara Zagora, Plovdiv and Sofia have been assigned under a specific



regulation of the Ministry of Health to perform certain genetic studies. If a genetic test is not included in a clinical pathway or is not funded by other mechanisms, it should be paid by the patient at rates set by the laboratory. Prices of genetic research vary from a few hundred to several thousand levs. In fact, the lack of regulated funding often restricts the access to genetic testing for those who need it.

The structures performing genetic counseling and / or diagnosis of oncological diseases in Bulgaria are the following: *Maichin Dom* University Hospital of Obstetrics and Gynecology, National Genetics Laboratory (Clinical Genetics Laboratory); National Specialized Hospital for Active Treatment of Hematological Diseases - EAD, Sofia, Laboratory of Cytogenetics and Molecular Genetics; Laboratory of Genomic Diagnostics, Center of Molecular Medicine, Department of Medical Chemistry and Biochemistry, Medical Faculty, Medical University – Sofia; *St. George* University General Hospital – Plovdiv, Department of Medical Genetics; *St. Marina* University General Hospital – Varna, Laboratory of Medical Genetics; *Dr. Georgi Stranski* University General Hospital – Pleven, Laboratory of Medical Genetics; the private laboratories *Genica* Genetic Medical Diagnostic Laboratory, Sofia; NUTRIGEN Ltd and NM Genomix (not performing tests, only obtaining material); *Nadezhda* Hospital, Sofia.

6. The situation of Education Programs regarding Oncogenetics:

The only educational program regarding oncogenetics in Bulgaria is “The Multidisciplinary Oncology Talks and Extracts” (in Bulgarian the abbreviation is MORE). This multidisciplinary conference is organized by the Bulgarian Oncological Scientific Society. It takes place every year and targets pathologists, molecular biologists, medical geneticists, medical oncologists, urologists, radiation therapists, radiologists, clinical laboratory physicians, and all other medical specialists involved in the diagnosis, treatment and prevention of cancer.

At this conference the National Expert Board (a multidisciplinary team including experts from several medical specialties and their national branch organizations) discusses and accepts the National Guide for clinical practice for cancer patients. This document provides advanced algorithms for molecular diagnostic testing and clinical use of validated



predictive biomarkers for the treatment of malignant solid tumors and haematological neoplasias according to their localization.

Oncogenetics is also part of the postgraduate courses in medical genetics and medical oncology specialties.

7. Identification of the practical need (infrastructure, human, and financial resources) for establishing and developing an Oncogenetic Network at the level of each country involved as a partner in the HOPE project.

In Bulgaria oncogenetic centers (situated in the medical universities) are needed for the purposes of providing care for cancer patients. In these centers a multidisciplinary team will be available to the cancer patients. These centers will organize training programs for specialists dealing with cancer patients, as well as for patients at risk for hereditary cancer, their families and the general public.

