

REPUBLIKA SLOVENIJA VLADA REPUBLIKE SLOVENIJE



## The National Cancer Control Programme 2017–2021

## SUMMARY

According to epidemiological indicators, cancer is a major public health burden in Slovenia, as it is the leading cause of death among men and number two among women. Furthermore, global indicators show that cancer is a modern-day epidemic.

The burden of cancer can only be systematically reduced in the long term if cancer is comprehensively controlled. For this purpose, the National Cancer Control Programme (NCCP) was established in 2010, which set goals to be achieved by 2015.

In the NCCP 2010–2015 period, a slower growth in cancer incidence was achieved, more so in women than in men. During this period cancer mortality decreased for both genders and the survival rate of cancer patients in Slovenia increased compared to previous periods.

The document of the NCCP 2017-2021, which was drafted in 2016 in cooperation with numerous stakeholders, defines the strategic objectives of the programme\_

; to reduce incidence, improve survival, and provide a greater quality of life for cancer patients. The Programme's strategic objectives can only be fulfilled through the coordinated efforts of all those segments of the healthcare system defined in the specific objectives forprimary and secondary prevention,, diagnostis and treatment, rehabilitation, palliative care, research, education, monitoring the burden of cancer, and information technology. In order to achieve each of these specific objectives of the Programme, measures, deadlines, and their responsible institutions have been defined.

Furthermore, the NCCP 2017–2021 also defines the updated and more operational programme management scheme that will enable a more transparent, competent, and professional control of one of the most complex systems within our healthcare structure.

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## 1. Purpose of the document

The National Cancer Control Programme (the NCCP) is a programme of activities, tasks and measures necessary for efficient action in the field of cancer control in the Republic of Slovenia. The NCCP is based on the findings of international and Slovenian studies and on the recommendations of European Union and the World Health Organisation. At the same time, it is adapted to the healthcare system of the Republic of Slovenia, which provides all of its citizens with the right to equal access to cancer-related healthcare services. The NCCP represents the views of the healthcare policy, the medical field, and the civil society with regard to cancer control.

The institution responsible for the National Cancer Control Programme is the Ministry of Health.

By means of strategic and specific goals, the **NCCP 2017–2021** upgrades the National **Cancer Control programme 2010–2015**, which defines in detail the areas in question and which was adopted by the Government of the Republic of Slovenia in 2010<sup>1</sup>. The basis for developing the NCCP 2017–2021 are the recommendations of the European Commission(European Guide for Quality National Cancer Control Ptogrammes, EPAAC project<sup>2</sup>).

Comprehensive cancer control is one of the most demanding segments in the entire healthcare system. and includes:

- the management and planning of all of the healthcare funds necessary for cancer control;
- cancer-related healthcare services that are coordinated, managed at a national level, and sustainably funded, including preventive actions, diagnostic procedures, treatment, and rehabilitation.

The purpose of the National Cancer Control Programme is to fulfil the strategic and specific objectives that are defined in detail in this document, namely for the next five-year period according to the following priority areas:

- to reduce the number of new patients (incidence), to increase survival rates and improve the quality of life of cancer patientspatients (*strategic goals*);
- to increase the significance of prevention, to increase the volume of preventive actions, to enable simple access to screening programmes to all target groups (*specific objectives of primary and secondary prevention*);
- to improve the comprehensive organisation of oncological healthcare activities at the primary, secondary, and tertiary healthcare levels, to increase human resource capacities and the amount of diagnostics and treatment equipment (*specific objectives of diagnostics and treatment*);
- to provide cancer patients with comprehensive rehabilitation at a national level (*specific objectives of comprehensive rehabilitation*);
- to ensure high-quality palliative care at a national level (*specific objectives of the National Programme for Palliative Care*);

<sup>&</sup>lt;sup>1</sup> The text of the NCCP 2010–2015, which defines the objectives, the mission, the vision, and the values and measures of the Programme for the past five-year period, is available here: <u>http://www.dpor.si/</u>

<sup>&</sup>lt;sup>2</sup> When drafting this document, we relied on the recommendations of the European Partnership for Action Against Cancer (EPPAC), which issued guidelines for drafting national cancer control plans. <u>http://www.epaac.eu/national-cancer-plans</u>

- to boost research and improve the education of experts as well as the population in the field of cancer (*specific objectives of research and education*);
- to coordinate the information technology of oncology centres at all healthcare levels with the e-zdravje project (e-Health) (*specific objectives for information technology*);
- to ensure a stable source for managing the national programme, including expert bodies that prepare expert guidelines, verifying quality indicators and comprehensively providing information and raising the awareness of all segments of the public (*specific objectives for programme management*).

## 2. Background

#### 2.1. The burden of cancer in Slovenia

In recent years, more than 13 thousand Slovenians per year have been diagnosed with cancer, i.e. more than seven thousand men and approximately six thousand women. Just over 5,800 of them die of cancer, i.e. about 3300 men and approximately 2500 women. There are nearly 90,000 people among us that have at some point been diagnosed with cancer (prevalence). Because cancer is more prevalent among the elderly (only one third of patients are younger than 65 when diagnosed) and the Slovenian population is ageing, it can be expected that the burden of this disease will continue to increase even if the level of risk factors remains the same as today. The crude cancer incidence and mortality rates are increasing; in the past 20 years, the crude incidence rate has almost doubled, and on average it has been increasing by 2.4% annually in the past decade (3.1% in men and 1.6% in women). On average, the crude mortality rate has been increasing by 1.5% annually in men and 1.7% annually in women. More than half of this increase is due to the ageing of the population, as longer life expectancy means that more people are likely to live long enough to be diagnosed. The age-standardised cumulative incidence rate shows that the cancer risk increase is slower. It is encouraging that the cancer-related mortality rate (not taking ageing into consideration) is decreasing, primarily since the mid-1990's, which indicates that treatment has been successful. In our opinion, more than 14,000 Slovenians will get cancer in 2016. Among those born in 2012, one of two men and one of three women will get cancer by the age of 75.

Cancer is not just one illness, but hundreds of different ones. These illnesses can occur in all tissues and organs of the human organism. They differ in frequency, treatment, and outcome, and they also have different risk factors, some better known, some less. The five most common types of cancer in Slovenia - skin (excluding melanoma), colorectal, prostate, breast, and lung cancers account for almost 60% of all new cancer cases. Cancers affecting these organs are related to an unhealthy lifestyle, excessive sunbathing, unhealthy diet, smoking, and excessive alcohol consumption; these risks must be reduced using primary prevention measures. In 2013, prostate cancer was the number one cancer in men accounting for 20% of all cancers affecting men; skin (excluding melanoma), lung, and colorectal cancers followed. The number one cancer affecting women in 2013 was skin cancer (excluding melanoma), followed by breast, colorectal, and lung cancers. Among the most frequent cancers in men in the past ten years, the incidence rate of prostate, skin (melanoma and non-melanoma cancer), and colorectal cancers increased the fastest. The incidence rate of lung and stomach cancers decreased. In women, the incidence rate of skin cancer (both types), colorectal, breast, and lung cancers increased the fastest, while the incidence of cervical cancer decreased. It is encouraging that since 2010 the incidence of colorectal cancer has decreased in both sexes.

The five-year relative survival rate of patients with any cancer type excluding nonmelanoma skin cancer, diagnosedl in the 2009–2013 period, was 54.7% in men and 59% in women, and it has been increasing over the years. The survival rate exceeded 80% in men with testicular cancer, thyroid cancer, Hodgkin's lymphoma, prostate cancer, and skin melanoma, and in women with thyroid cancer, skin melanoma, Hodgkin's lymphoma, breast cancer, and cervical cancer.

Among those who were diagnosed in 2013, 82% underwent specific oncological treatment; 63% of patients were operated on within their first treatment, 28% of patients underwent systemic treatment, the availability of which was very good in this period, and 22% received radiation treatment. Compared to European countries, significantly fewer patients with prostate cancer received radiation therapy during their first treatment. A third of initial surgeries are performed at the Ljubljana University Medical Centre, more than a thousand initial surgical procedures per year are also performed at the University Medical Centre Maribor and the Institute of Oncology Ljubljana, and more than 250 are performed at the Celje, Slovenj Gradec, Novo Mesto, Murska Sobota, Nova Gorica, Jesenica, and Izola general hospitals. Two thirds of patients receiving systemic treatment undergo such treatment at the Institute of Oncology Ljubljana, 10% at the University Medical Centre Maribor and approximately 150 patients at the Golnik Clinic. Fewer than 70 patients a year receive systemic treatment from other individual providers. For now, all patients receive radiation at the Institute of Oncology Ljubljana.

Collecting data on cancer patients has had a long tradition in Slovenia, as the Institute of Oncology Ljubljana has one of the oldest cancer population registers in Europe, the Cancer Registry of the Republic of Slovenia (hereinafter: RRRS). It was established in 1950 as a special service for collecting and processing data on the incidence, prevalence, and survival of cancer patients. This data, together with mortality data collected and processed by the National Institute of Public Health, serve as the basis for evaluating the burden of cancer in our country. The data are important for planning and monitoring the National Cancer Control programme in the fields of primary and secondary prevention, diagnostics, treatment, and rehabilitation, for planning capabilities and the resources required to control cancer (human resources, medical equipment, bed capacities); it is also valuable for clinical and epidemiological studies in Slovenia as well as for broader international studies and for evaluating the effectiveness of screening programmes.

In Slovenia, **cancer registration** is mandatory and it has been laid down by law since the foundation of the Cancer Registry. The basic source of information is cancer registration forms that are sent to the Cancer Registry from all hospitals and diagnostic centres in Slovenia. These cancer registration forms are used to collect personal data, data on the illness type (location, morphology, stage), and treatment type. By being connected to the collection of the causes of death, screening programme registries, and the Central Population Register, the RRRS increases the completeness and quality of data.

#### 2.2. Background for drafting the NCCP 2017–2021

#### 2.2.1. Recommendations of the EU and the World Health Organisation

By developing the National Cancer Control Programme in 2010, the Republic of Slovenia responded to the recommendations of the European Union and the World Health

Organisation intended for all member states and relating to cancer control at a national level.

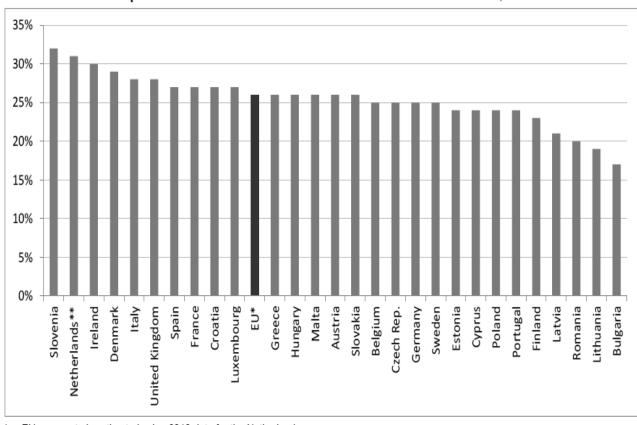
The main objective of the European Partnership for Action Against Cancer co-funded by the European Commission, more precisely the Directorate General for Health and Consumers (DG SANCO), is to use cancer control measures to decrease the number of new cancer cases in EU Member States by 15% by 2020.

In developing SMART objectives for individual programme components, the NCCP 2017–2021 follows EPAAC guidelines (<u>EPAAC</u> – European Partnership Action Against Cancer) and also the recommendations for planning cancer control activities on the vertical and horizontal healthcare levels (Guide for Quality National Cancer Control Ptogrammes),.

#### 2.2.2. Epidemiologic situation in Slovenia

Cancer has become the most significant health issue in Slovenia, as it is the number one cause of mortality in men and number two in women; with regard to the proportion of deaths due to cancer, Slovenia is number one among EU countries (Figure 1, EUROSTAT News release, February 2016). Furthermore, Slovenia ranks in the eighth highest place compared to other European countries with regard to the incidence and mortality due to cancer (Figure 2, EUCAN 2012). In the field of comprehensive rehabilitation of cancer patients, we have been unable to establish systemic solutions in the past five-year period, and palliative care is also insufficiently provided.

Figure 1: Proportion of deaths due to cancer in EU Member States, EUROSTAT 2016.



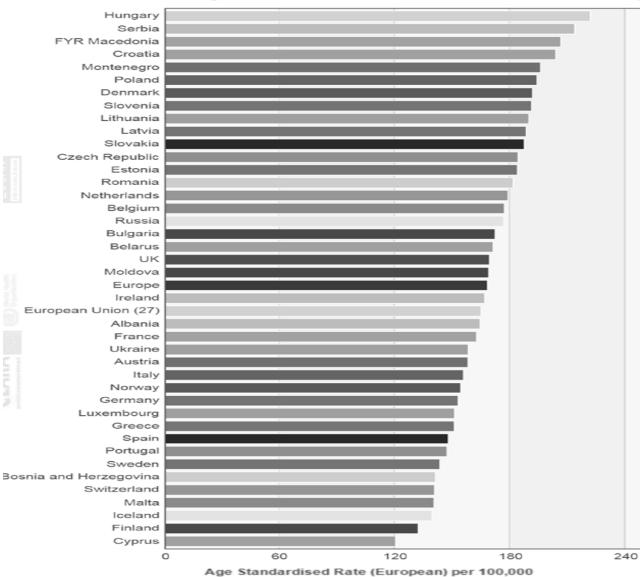
Proportion of deaths due to cancer in the EU Member States, 2013

\* EU aggregate is estimated using 2012 data for the Netherlands.

\*\* 2012 data instead of 2013.

### Highest share of deaths due to cancer in Slovenia and the Netherlands

Figure 2: Estimated mortality due to cancer (all sites but non-melanoma skin cancer), EUCAN 2012



#### Estimated mortality of all sites but non-melanoma skin in both sexes,

## 3. The process of drafting the NCCP 2017–2021

The National Cancer Control Programme 2017–2021 is conceived as an action plan upgrading the National Cancer Control Programme (NCCP) 2010–2015.

The process for the drafting of the NCCP 2017–2021 was introduced to the stakeholders of the Programme by means of **a public presentation**, which took place at the Ministry of Health in March 2016. This presentation of the process and the planned time-line involved the representatives of the Ministry of Health, the National Public Health Institute, the Institute of Oncology Ljubljana, the Cancer Registry, the Health Insurance Institute of the Republic of Slovenia, the representatives of primary, secondary, and tertiary healthcare dealing with oncology, and many members of the civil society. In their discussions, weaknesses of the previous NCCP 2010–2015 were defined and expressed expectations for the NCCP 2017–2021, including the wish to more actively involve primary healthcare, to systemically regulate cancer treatment according to the achieved standards for particular types of treatment and according to a transparent and effective programme management method.

In order to enable the stakeholders to draft a comprehensive situation analysis of the NCCP 2010–2015, an NCCP 2010–2015 SWOT analysis was carried out in the spring of 2016 by means of an online survey involving more than 70 Programme stakeholders.

The summary of the results of this analysis that stressed the strengths, weaknesses, and opportunities of, and threats to, the NCCP 2010–2015 for the planning of the Programme in the next five-year period was discussed by the participants of **a workshop in July 2016**. This workshop involved the representatives of the Ministry of Health, the National Public Health Institute, the Institute of Oncology Ljubljana, the Cancer Registry, and the Health Insurance Institute of the Republic of Slovenia. The workshop defined the groundwork for the upgrade of the Programme management structure and the recommendations for mechanisms that will enable the monitoring of the Programme at a systemic and short-term level, noting any errors in the treatment of oncology patients. **In November 2016**, the representatives of the NCCP 2017–2020, the powers and responsibilities of the management bodies of the NCCP 2017–2021, and provided recommendations for improvements.

**Workshops** for the drafting of the specific objectives and measures for the next five-year period, focusing on their substance, took place in the fields of **comprehensive rehabilitation** (in May and October 2016) and **palliative care** (September 2016). In order to draft specific objectives and measures in the fields of **primary and secondary prevention, diagnostics and treatment, education,** and **research**, more than 30 meetings were held in 2016 with leading experts in these fields, at which recommendations for the improvement of the current situation were devised.

Following European recommendations, in total more than one hundred competent participants collaborated on the drafting of the NCCP 2017–2021; these participants represented the interests of healthcare policies, the healthcare fund provider, the medical and epidemiological fields, and of cancer patients integrated into various non-governmental organisations.

# 3. The analysis of the National Cancer Control Programme 2010-2015

In addition to taking into account the European EPAAC recommendations, the strategic and specific objectives of the National Cancer Control Programme 2017–2021 were devised based on the analyses of the achievements of the previous five-year period in which the Programme was implemented and of its challenges, and on the Programme SWOT analysis.

#### a. Achievements in the past five-year period

The achievements of the National Cancer Control Programme 2010–2015 include the fulfilment of the set strategic objectives, namely: the slowing down of cancer incidence in women and, to a lesser extent, in men; mortality significantly decreased in both sexes, but to a lesser extent than planned; compared to previous periods, the objective of increasing the five-year survival rate from the start of cancer treatment has been fulfilled in both sexes.

A decrease in the smoking of men and a decrease in alcohol consumption was noticed In the previous NCCP implementation period. Significant shifts in decreasing the incidence of colorectal cancer and cervical cancer were achieved in the field of screening programmes. The National Breast Cancer Screening Programme DORA began spreading throughout the country. In the most extensive field within the National Cancer Control programme – diagnostics and treatment – an expert consensus was reached on how to establish a network of oncology activities at the secondary and tertiary healthcare levels. Some shifts have also been achieved in palliative care, but not all objectives have been fulfilled; in the field of comprehensive rehabilitation, none of the set objectives were fulfilled.

The NCCP 2010–2015 Report on Achievements and Challenges was confirmed by the members of the final session of the first-term NCCP Medical Council on 2 December 2015. In detail, the achievements of the NCCP 2010–2015 include:

- Strategic Programme objectives:
  - In the period from 2004/05 to 2011/12, the achievement of Programme objectives is evident from:
    - the increase of the age-standardised incidence in women by +1.4% (objective: a maximum of +8% by 2015), +6.8% in men (objective: a maximum of +5% by 2015);
    - the decrease of the age-standardised mortality rate by -6.4% in men and 3.7% in women (objective: 10% for both sexes by 2015).
  - The improvement of the five-year relative survival rate of patients in 2009/10 compared to the 2001–2005 period: by 9% in men (objective: 10% from 2010 to 2015) and 2.4% in women (objective: 2% from 2010 to 2015).
- Primary prevention: a significant reduction in the number of smokers among men, less harmful alcohol consumption as a result of the adopted legislation.
- Secondary prevention:

- The ZORA Programme: cervical cancer incidence has decreased by half in Slovenia.
- The SVIT Screening Programme: the cancer discovered in 70% of the programme participants is limited to the colon and rectum; prior to the implementation of the SVIT Programme, this percentage was only 12–14%, so this is a very significant achievement of the screening programme. In 2011, 2012, and 2013, we noticed for the first time a decrease in the incidence of colorectal cancer by 10% per year. Since June 2015, people up to the age of 75 have also been included in the programme (at start up to 70 years).
- The DORA Programme: a plan for spreading the programme throughout Slovenia, including a time-line, was devised in 2015; the implementation of this plan also began in the same year. The Programme began spreading to the entire area of Slovenia.
- Diagnostics and treatment:
  - Professional Boards created a proposition for a network of oncological centers.
  - Reducing the waiting period for radiation treatment.
- Palliative care:
  - Appointment of a coordinator of the National Programme for Palliative Care.
  - Provision of a number of educational courses for palliative care providers.
  - The Metulj website: <u>www.paliativnaoskrba.si</u>.
- Research:
  - Including cancer patients in clinical studies (8% of cancer patients are included in clinical studies); a list of cancer studies was published online.
- Programme management and the monitoring of the burden of cancer:
  - The SLORA website: Cancer data is available (in Slovenian and English) on the website of the Cancer Registry of the Republic of Slovenia <u>www.slora.si</u>.
  - The NCCP website: visit <u>www.dpor.si</u> to find information on how the NCCP is being implemented (in Slovenian and English) and minutes from all meetings and all annual reports.

### b. SWOT analysis

The SWOT analysis was carried out in the spring of 2016 based on an anonymous online survey. A broad spectrum of Programme stakeholders were invited to complete the survey: the representatives of organisations implementing healthcare policies, the human resources in primary, secondary, and tertiary healthcare, and the civil society.

#### Strengths:

- 1. The Programme serves as a guideline for implementing healthcare policy measures, including providing guidance for development.
- 2. The Programme is the most important document regulating at a state level all activities within the prevention, diagnostics and treatment of oncological diseases, and establishing reference diagnostics and therapy centres for the comprehensive treatment of patients.
- 3. It connects all key stakeholders in the field of oncology in order to ease the burden of cancer.

- 4. The Programme has set objectives for the comprehensive treatment of a complex issue.
- 5. In the long term, it identifies priority tasks in oncology at a state level.
- 6. It provides a comprehensive approach to planning the treatment of cancer patients, including multidisciplinary treatment.
- 7. It leads to the development of common guidelines and protocols in oncology.
- 8. It recommends targeted, in-depth, and requisite education in oncology.
- 9. It promotes the standardisation of data collection and reporting related to cancer treatment.
- 10. It supports the introduction of electronic methods of managing and monitoring cancer patients.

#### Weaknesses:

- 1. The Programme does not have any defined resources (human resources, premises, equipment) for performing activities.
- 2. There are no clear definitions of expert and organisational criteria to be used for implementing a particular oncological activity.
- 3. The document is not binding for all institutions involved; it does not enjoy consistent support from relevant stakeholders, such as the Ministry of Health, the Health Insurance Institute of Slovenia, the Medical Chamber of Slovenia, and experts.
- 4. The Programme does not have any leverage to eliminate those activities from the oncological programme that prove to be inefficient.
- 5. The Programme does not include a network of reference centres for the comprehensive treatment of cancer according to individual diagnoses.
- 6. There is a lack of information exchange among stakeholders and an insufficient use of modern information technologies.
- 7. The Programme does not have an action plan in each field for the establishment of expert doctrines.
- 8. The Programme is only on paper and is only discussed at the annual meeting of stakeholders.
- 9. There is insufficient emphasis on comprehensive treatment, palliative care, and nutritional support.
- 10. There is a lack of clinical registries for monitoring cancer patients.
- 11. Citizens do not have access to medical institutions which are best equipped to treat particular cancer types.

#### **Opportunities:**

- 1. To establish expert and financial supervision.
- 2. To improve all aspects of the treatment of cancer patients: equal opportunities for all patients, expert and prompt treatment, improvement of survival and quality of life, full-scale monitoring and planning of measures, reduction of total costs.
- 3. To reduce costs by implementing greater cost efficiency.

- 4. To draft a full strategic plan on the basis of epidemiological data and situation analysis, which will determine the institutions involved, accreditation conditions and effectiveness monitoring, and quality and financial efficiency indicators.
- 5. To educate primary healthcare staff, specialists, and other healthcare human resources.
- 6. The NCCP is an opportunity for the reform of the healthcare system in the field of oncology.
- 7. Greater promotion of prevention and screening programmes.
- 8. To reduce the burden of cancer by means of a strategy with preventive measures and early detection.
- 9. To provide patients with equal access to optimum treatment and rehabilitation.
- 10. To monitor and provide high-quality treatment of patients following their completed primary-level treatment.
- 11. Better exchange of information among stakeholders.

#### Threats:

- 1. Political interests and the lack of political will for implementing the Programme, inconsistent healthcare policies.
- 2. Lack of human and financial resources for implementing the planned measures.
- 3. Lack of guidelines/clinical pathways for cancer patients, including the primary healthcare level.
- 4. The interests of individual expert groups.
- 5. The Programme is insufficiently formally binding; it is too general, too extensive, and not operational.
- 6. Lack of indicators and accreditation conditions for safe and high-quality treatment.
- 7. Allowing dispersion and lack of control due to the ambitions/influences/interests of individuals or institutions.
- 8. Adopting objectives without a financial assessment and provided funds for their implementation, including human resource support.
- 9. Abandonment of expert criteria, insufficient expert knowledge.
- 10. Insufficient information support.
- 11. Waiting periods are too long.

## 4. The strategic and specific goals of the National Cancer Control Programme 2017-2021

#### a. Strategic goals

The NCCP 2017–2021 strategic goals are<sup>3</sup>:

- **To slow down the increase in cancer incidence:** to use effective primary and secondary prevention in order to reduce the number of cancers that we ascribe to preventable risk factors; in 2021, up to 15,500 people will get cancer, of which nine thousand will be men and up to 6,500 will be women.
- **To increase survival rates: by** early diagnosis and high-quality treatment keep the five-year relative survival rate in both sexes above the European average; to improve the five-year relative survival rate by 10% in cancer patients diagnosed between 2017 and 2021 compared to those in the 2007–2011 period.
- To improve the quality of life of cancer patients by using psychosocial and physical rehabilitation, and to improve the proportion of patients with advanced-stage illness who receive palliative care.

### b. Specific goals

The strategic goals can be achieved by means of activities for fulfilling the specific goals of the Programme, which have been devised for primary and secondary prevention, diagnostics and treatment, comprehensive rehabilitation, palliative care, research and education, and the development of a support environment – information technology – for all three healthcare levels (primary, secondary, and tertiary).

#### i. Primary prevention

With primary preventive measures we can prevent up to 40% of all cancer types by managing key risk factors, such as smoking, harmful and risky alcohol consumption, unhealthy diet, lack of physical activity, and excessive weight and obesity, excessive sunbathing, and the exposure to carcinogenic substances in one's working and living environments. By closely collaborating on developing environmental, professional, and healthcare legislation, primary prevention will contribute considerably to achieving the strategic goals of the NCCP 2017–2021. The primary prevention objectives and measures for the next five-year period are compliant with the recommendations defined in the European Code Against Cancer<sup>4</sup>. In Slovenia, long-term strategic documents and relevant legislation have already been adopted in all of the aforementioned fields.

<sup>&</sup>lt;sup>3</sup> The strategic objectives have been developed based on the definition of the terms listed in Chapter 9: *Glossary of terms used*.

<sup>&</sup>lt;sup>4</sup> http://www.onko-i.si/uploads/media/Evropski\_kodeks\_proti\_raku\_2014.pdf

In the field of primary prevention, the following objectives and measures will be pursued by 2021:

#### Tobacco

Tobacco is the leading preventable risk factor for numerous cancer types, cardiovascular and respiratory diseases, and many other diseases. New legislation in this field was adopted in early 2017. The proposed new act lays down a comprehensive programme with measures, the objectives of which include reducing the number of children, young people, and young adults beginning to smoke and continuing to smoke, encouraging people to quit smoking, and reducing the exposure to tobacco smoke in the environment.

**Objective 1<sup>5</sup>:** To reduce the proportion of smokers in the 15 to 64 age group from 24% to 19%, and to reduce the sale of tobacco products (cigarettes and fine-cut tobacco) by 30%. Responsible institution: Ministry of Health in cooperation with stakeholders.

- **Measure 1:** The Act governing tobacco and tobacco products was adopted in early 2017; to raise tobacco product prices. Responsible institutions: Ministry of Health and Ministry of Finance
- **Measure 2**: To support programmes helping people to quit smoking and preventing smoking. Responsible institution: Ministry of Health

#### Nutrition and exercise

Because suitable nutrition and regular physical activities are significant factors protecting health and preventing chronic illnesses, including cancer, the Ministry of Health will fulfil the objectives and carry out the measures arising from the 2015–2025 National Programme on Nutrition and Physical Activity for Health. This document defines 10 strategic objectives with the purpose of improving the dietary habits of the population, increasing physical activity, and reducing the sedentary lifestyle in all population groups, thereby guaranteeing that an energy and nutrient balance between metabolism needs and nutrient intake is achieved. This serves as the groundwork for establishing conditions required for the optimum nutritional status of the population, especially of children and the elderly, i.e. reducing the incidence of obesity or malnutrition in particular target groups. The indirect key challenge of the National Programme is to contribute to the decrease in the incidence of chronic illnesses, including cancer. The objectives have been summarised based on the 2015–2025 National Programme on Nutrition and Physical Activity for Health, Bon Appetit Slovenia.

**Objective 1**: To increase the proportion of six-month-old breast-fed children to 20% and to increase the proportion of 12-month-old breast-fed children, who are also given suitable supplementary food, to 40%.

**Objective 2:** To increase the proportion of the population eating vegetables at least once a day by 10%, and to reduce the difference between the sexes.

**Objective 3:** To increase the proportion of the population eating fruit at least once a day by 5%, and to reduce the difference between the sexes.

**Objective 4:** To increase the proportion of the physically active population by 10%.

**Objective 5<sup>6</sup>:** To reduce the proportion of overfed and obese children and young people by 10% and to reduce the proportion of overfed and obese adults by 5%.

<sup>&</sup>lt;sup>5</sup> EHIS study.

**Objective 6:** To reduce the proportion of the population that frequently drinks sweet beverages, eat sweets and desserts by 15%.

**Objective 7:** To reduce salt intake in the population by 15%.

**Objective 8:** To reduce trans fat and saturated fat content in foodstuffs.

**Objective 9:** To reduce the proportion of malnourished and functionally less capable elderly people and patients.

 Measure 1: In the first quarter of 2017, the Government of the Republic of Slovenia plans to adopt the Action Plan for the Implementation of the Resolution on the National Programme on Nutrition and Physical Activity for Health 2015–2025 including the measures for fulfilling the above objectives in the 2016–2018 period. Responsible institution: Ministry of Health in cooperation with stakeholders.

#### Alcohol

It has been proved that, by consuming alcohol, the risk of numerous cancer types increases; therefore, the Ministry of Health will enhance its activities in this field.

**Objective 1**<sup>7</sup>: To reduce the proportion of excessive alcohol drinkers from 10.2% to eight percent. Responsible institution: Ministry of Health in cooperation with stakeholders.

**Objective 2<sup>8</sup>:** To reduce the proportion of 15-year-olds who have already drunk alcohol at 13 or younger from 40% to 35%. Responsible institution: Ministry of Health in cooperation with stakeholders.

- **Measure 1:** Adopt a comprehensive national alcohol policy, including implementation plans, by 2021. Responsible institution: Ministry of Health
- **Measure 2:** Amend the relevant legislation by 2021 in order to ensure greater effectiveness of actions taken. Responsible institution: Ministry of Health
- **Measure 3:** To develop a model for the treatment of those people whose alcohol drinking habits are risky and harmful by 2021, and to help their family members. Responsible institution: Ministry of Health

#### Exposure to the sun and tanning beds

**Objective 1**: To reduce the exposure to the sun and tanning beds of all generations, younger ones in particular. Responsible institution: Ministry of Health in cooperation with stakeholders.

- **Measure 1:** Raising the awareness of young people on the harmful effect of exposure to sun and artificial sources of ultraviolet radiation (tanning beds). Responsible institution: NIPH
- **Measure 2:** To study the possibility of a legislative ban on the use of tanning beds by those younger than 18. Responsible institution: Ministry of Health
- Measure 3: To implement a stricter official control over the activities carried out by salons with tanning beds for personal grooming purposes, namely by means of targeted joint actions by the Health Inspectorate of the Republic of Slovenia (ZIRS) and the Market Inspectorate of the Republic of Slovenia (TIRS). Responsible institutions: ZIRS, TIRS.

<sup>8</sup> HBSC study.

<sup>&</sup>lt;sup>6</sup> Measuring objectives by means of HBSC, EHIS, CINDI studies

<sup>&</sup>lt;sup>7</sup> The CINDI study and the study: The Use of Tobacco, Alcohol, and Illicit Drugs.

• **Measure 4:** To support the preventive project titled Sun Safety (Varno s soncem), which warns of the importance of proper protection against the harmful effects of sun rays. Responsible institution: NIPH

#### The working environment

**Objective 1:** To consistently implement legislation on the safety and health at work by stressing improved risk assessments, especially in workplaces and in living environments that are exposed to carcinogens. Responsible institution: Ministry of Health in cooperation with stakeholders.

- **Measure 1:** To adopt rules on occupational diseases in 2017. Responsible institution: Ministry of Health
- **Measure 2:** To adopt a new strategy on safety and health at work in 2018. Responsible institutions: Ministry of Labour, Family and Social Affairs (MDDSZ) and the Ministry of Health (MZ).

The living and working environment:

- **Measure 3:** To increase awareness raising related to occupational cancers. Responsible institutions: Ministry of Labour, Family and Social Affairs (MDDSZ) and the Ministry of Health (MZ).
- **Measure 4:** To adopt National Guidelines on Asbestos and the Performance of Activities. Responsible institution: Ministry of Health in cooperation with stakeholders.

### Ionising radiation

#### Radon:

**Objective 1**: To use structural measures at an interministerial level in order to restrict the exposure to radon in public and private buildings in the country by 2020. Responsible institution: Ministry of Health

- **Measure 1:** To include the verification of radon levels and measures for its prevention in the Construction Act and in other implemented regulations governing this field by 2019. Responsible institutions: Slovenian Radiation Protection Administration and Ministry of the Environment and Spatial Planning.
- **Measure 2:** To transpose the content of the Directive 2013/59/Euratom into Slovenian legislation by the end of 2018. Responsible institution: Ministry of Health.
- **Measure 3:** To define areas in Slovenia with increased radon levels by the end of 2018. To draft a map showing radon levels throughout the country by the end of 2020. Responsible institution: Slovenian Radiation Protection Administration
- **Measure 4:** To ensure by 2020 occasional radon level measurements in the residential facilities of individuals in order to determine these levels.

#### Infections linked to cancer (HPV, hepatitis B infections)

Immunisation against hepatitis B is a part of the compulsory immunisation programme. Immunisation of girls against HPV is non-compulsory and is also a part of the immunisation programme. Both immunisations are financed using compulsory health insurance funds.

**1. objective:** To ensure at least a 75% rate of immunisation of girls (11 and 12 years old) against HPV by the end of 2021. Responsible institution: NIPH

- **Measure 1:** To continually promote immunisation against HPV and to raise the awareness of various target groups concerning the benefits of immunisation.
- **Measure 2:** To study the possibility of introducing immunisation against HPV for boys.

**Objective 2**: To maintain a high rate of immunisation (proportion of immunised people) against hepatitis B (approx. 90%). Responsible institution: NIPH

• **Measure 1:** To promote immunisation.

#### Enhancing preventive approaches in primary health care

Preventive programmes will be upgraded and expanded with the goal of achieving more successful prevention and management of chronic diseases and other conditions, especially in the light of the specific needs of vulnerable groups and the elderly population, who do not utilise preventive services to their full extent.

**Objective 1:** To include 70% of the population in prevention programmes by 2021. Responsible institutions: Ministry of Health, NIPH

- **Measure 1:** To upgrade and develop prevention programmes and to implement them in primary healthcare and in the local community.
- **Measure 2:** To adapt prevention programmes to the specific needs of vulnerable groups.

#### ii. Secondary prevention

Secondary prevention encompasses early cancer discovery, as the treatment of the majority of cancer types is more successful if cancer is discovered at an early stage. For particular cancer types, organised screenings allow us to discover the patients for whom there is a high likelihood that they have a preinvasive or early invasive form of cancer, which does not yet cause any clinical issues. The significant aspect of the DORA, SVIT, and ZORA screening programmes is to actively extend invitations to individual population groups to be tested and to monitor programme indicators, as these programmes can only be effective if they include a minimum of 70% of the target population, or 65% in the case of colorectal cancer.

The horizontal objectives of the ZORA, SVIT, and DORA screening programmes are:

**Objective 1**: to adopt the legislation on Screening Programmes by the end of 2017.

**Objective 2**: To amend and adopt an act on databases by the end of 2018.

#### 1. DORA – the National Breast Cancer Screening Programme

DORA is the National Breast Cancer Screening Programme organised by the Institute of Oncology Ljubljana in cooperation with the Ministry of Health and the Health Insurance Institute of Slovenia. DORA operates in accordance with the European guidelines for guaranteeing the quality of breast cancer screening and diagnostics. The programme provides treatment for women between the ages of 50 and 69, who are invited to undergo preventive mammography every two years. The objective of the DORA programme is to decrease the breast cancer mortality rate in the examined group of women by 25–30%. The strategic objectives of the programme are also defined in the *DORA 2015–2020 Strategic Plan*, and the measures for their fulfilment are defined in greater detail in its appendices (mainly in the *2015–2020 DORA Programme Expansion Plan*).

**Objective 1:** To develop a sustainable management system and stable national infrastructure for the effective implementation of the DORA programme in accordance with the defined European quality standards by the end of 2016. Responsible institution: Institute of Oncology Ljubljana

**Objective 2:** To achieve a particular standard in Slovenia by the end of 2017, namely that every suitable female inhabitant between the ages of 50 and 69 receives a personal invitation every other year to be examined at their closest DORA screening unit. Responsible institution: Institute of Oncology Ljubljana

**Objective 3:** By 2020, the average achieved participation in the DORA programme in every Regional Unit of the Health Insurance Institute of Slovenia is to be more than 70%; 10 years after the entire population has been covered, the breast cancer mortality rate in the screened population is to be reduced by 25%, with the satisfaction of the women involved exceeding the average satisfaction in the EU. Responsible institution: Institute of Oncology Ljubljana

#### 2. ZORA – the National Programme for the Early Detection of Precancerous Changes of the Cervix

The purpose of the ZORA programme is to achieve, by 2021, a 73–75% three-year coverage of the ZORA National Programme target population and to maintain the incidence of cervical cancer between 100 and 120 new cases of this cancer type per year.

This purpose can be achieved by fulfilling the following objectives:

**Objective 1:** To introduce to the Health Council by the end of 2020 a renewed cervical cancer screening policy pursuant to the Amendments to the European Guidelines for Quality Assurance in Cervical Cancer. Responsible institution: Institute of Oncology Ljubljana

- **Measure 1**: A proposal for the amended screening policy will be drafted in cooperation with the programme stakeholders for the Health Council by the end of 2020.
- **Measure 2**: By the end of 2021, a uniform method for HPV testing will be provided at a national level.

**Objective 2**: To update and amend the ZORA programme information system by the end of 2019. Responsible institution: Institute of Oncology Ljubljana in cooperation with the providers of the ZORA programme

- **Measure 1**: All women receive a written invitation to a screening examination from the ZORA Screening Centre at the Institute of Oncology Ljubljana or from their selected gynaecologist.
- **Measure 2**: All women receive a written notification concerning the results of the screening examination with instructions for further action.

- **Measure 3**: All providers of the ZORA National Programme are linked to the new e-Zora information system, so that access to the data required for the suitable treatment of women is available to all.
- **Measure 4**: The cervical histology and colposcopy test results will be standardised and structured by the end of 2018, and by the end of 2019 the test results will be collected in the ZORA register.

**Objective 3**: To develop binding standards for the providers of the ZORA National Programme by the end of 2018. Responsible institution: Institute of Oncology Ljubljana in cooperation with expert groups.

- **Measure 1**: Expert groups from relevant specialised fields must update/develop standards for cytology, histology, and HPV laboratories.
- **Measure 2**: Expert groups must update/develop standards in the diagnostics and treatment of precancerous and cancerous lesions.

#### 3. SVIT – the National Screening and Early Detection Programme for Colorectal Cancer

The National Screening Programme for Colorectal Cancer is organised by the National Institute of Public Health in cooperation with the Ministry of Health and the Health Insurance Institute of Slovenia.

**Objective 1**: To establish a sustainable screening programme management system by 2017, including expert guidelines and quality control. Responsible institution: NIPH

- **Measure 1**: To enable access by the end of 2017, namely through a network of colonoscopy centres and providers to colonoscopies following a positive screening test within one month.
- **Measure 2**: To adopt a legislative basis for the SVIT Screening Programme register and a link to the Cancer Registry by the end of 2017, and with the colorectal cancer register once it is established (see the objectives and measures in the chapter titled *Monitoring the burden of cancer*). Responsible institution: Ministry of Health
- **Measure 3**: To provide online updating of population data through a central population register by the end of 2017.

**Objective 2**: To increase the participation in the SVIT programme to 65% for all target population groups by the end of 2019. Responsible institution: National Institute of Public Health (NIPH).

- **Measure 1**: To actively include selected family doctors in the encouragement of nonresponsive individuals from the defined population by the end of 2017.
- **Measure 2**: To more actively include community nursing services in the inclusion of non-responsive individuals into the SVIT programme by the end of 2017.
- **Measure 3**: To enable the possibility of electronic sign-up for the participation in testing by the end of 2018.

#### iii. Diagnostis and treatment

The diagnostis and treatment of cancer are complex processes requiring the collaboration of numerous healthcare activities. Modern cancer treatment requires oncology-oriented specialist surgeons, radiologists, and medical oncologists, who provide a multi-disciplinary approach. This multi-disciplinary process also includes psycho-oncology, pharmacy, dietetics, rehabilitation, and nursing.

The National Cancer Control Programme 2017–2021 will endeavour to fulfil six horizontal objectives in diagnostis and treatment as one of the priorities of the entire Programme:

- **1. objective:** Upon first treatment, all patients are to be presented to the multi-disciplinary team<sup>9</sup> in a uniform and comprehensive manner by the end of 2018. Responsible institutions: The Institute of Oncology Ljubljana, oncology centres at the secondary and tertiary healthcare levels.
- 2. objective: The Guidelines for Diagnostis and Treatment for all cancer types are prepared until the end of 2018 and published on www.dpor.si; they are subsequently updated every year. Responsible institutions: multidisciplinary teams at the Institute of Oncology Ljubljana cooperating with experts from other tertiary institutions.
- 3. objective: To draft a situation analysis and an assessment of human resource needs for cancer treatment, which is revised every two years, by the end of 2017, taking into consideration incidence trends and new evidence-supported therapies. Responsible institutions: The Ministry of Health and the Health Insurance Institute of Slovenia in cooperation with coordinators of medical specialisation and training (surgical oncology, medical oncology, radiation therapy and oncology).
- 4. objective: To monitor the implementation of diagnostis and treatment in the Republic of Slovenia by the end of 2019, according to quality control indicators defined beforehand<sup>10</sup>.
- 5. objective: To establish a network of operating oncology centres for systemic treatment/surgical treatment/radiation therapy by the end of 2020. More detailed measures for fulfilling this objective are listed under the components of systemic treatment, surgical treatment, and radiation therapy below and in Chapter 7 -Management.
- 6. objective: Special attention is paid to the treatment of rare cancer types (incidence < 6/100,000). In Slovenia, rare cancer types are treated in institutions recommended by the Professional Board (hereinafter: PB RSK) in the NCCP 2010–2015<sup>11</sup>. Connections to these centres are to be established by 2021 (or when European Reference Networks for rare cancers are established).

The objectives and measures for particular fields in diagnostics and treatment are devised below, separately for the primary, secondary/tertiary healthcare levels.

<sup>&</sup>lt;sup>9</sup> Multidisciplinary consultation teams making decisions on treatment consist of, at least: a specialist surgeon, a radiation therapist/oncologist, and medical oncologists for frequent cancer types; in other cancer types, a diagnostic imaging specialist and a pathologist/cytologist are also required.

The fulfilment of this objective depends on the fulfilment of the objectives within the component Monitoring the burden of *cancer* or the component *Cancer Registry*.<sup>11</sup> The list of the public healthcare institutions recommended by the EPB for oncology is posted on www.dpor.si.

#### 1. Primary healthcare / Diagnosis and treatment

By actively including family doctors into cancer diagnostis and treatment, patients can be more quickly referred, waiting queues can be reduced, shorter patient pathways for some treatments can be ensured, and a better comprehensive treatment of patients with referrals to other treatment levels can be provided.

The specific objectives of primary healthcare relating to diagnostics and treatment are:

- objective: Comprehensive guidelines for the early diagnosis of cancer in primary healthcare will enter into force by the end of 2018; they are published on <u>www.dpor.si</u>. Responsible institution: Department of Family Medicine, Faculty of Medicine, University of Ljubljana.
- **Measure 1**: To revise all Slovenian and foreign guidelines for the early diagnosis in oncology for primary healthcare and to propose amended guidelines for the Slovenian healthcare system by the end of 2017.
- **Measure 2**: These guidelines are presented and confirmed by PB for family medicine and oncology by mid-2018.
- **Measure 3**: The confirmed version of the guidelines will be posted on <u>www.dpor.si</u> and in the Slovenian Medical Journal (Zdravniški vestnik) or in any other relevant Slovenian medical journal by the end of 2018, and the notification concerning the guidelines will be received by primary healthcare physicians, who may participate in training courses pertaining to the guidelines in 2019.
- 2. objective: To introduce priority referrals by the end of 2019 if a malignancy is suspected, taking into account the set deadlines for diagnosis and treatment, based on the adopted guidelines for the field of early diagnosis in oncology within primary healthcare. Responsible institution: Chair of Family Medicine, Faculty of Medicine, University of Ljubljana.
- **3. objective:** To carry out a cross-sectional study in early cancer detection in the field of primary healthcare by the end of 2021. Responsible institution: Chairt of Family Medicine, Faculty of Medicine, University of Ljubljana, in cooperation with the Institute of Oncology Ljubljana and the Ministry of Health.
- **Measure 1**: The cross-sectional study concerning the state of early diagnosis in oncology within primary healthcare at a national level will be a topic of a research paper (doctoral thesis) mentored by the Department of Family Medicine and co-mentored by the Institute of Oncology Ljubljana by the end of 2017.
- 4. **objective:** To transfer selected specialist cancer treatments with subcutaneous or intramuscular drug administration, together with laboratory testing from the secondary and tertiary levels, to the primary healthcare level by the end of 2019. Responsible institution: The professional representative of family physicians in the Republic of Slovenia in cooperation with the Institute of Oncology Ljubljana and the Health Insurance Institute of Slovenia.
- **Measure 1**: Standardised clinical pathways for selected treatments dealt with by the PB for oncology and family medicine will be devised by the end of 2018.

**5. objective:** As of the beginning of 2018, all oncology centres at the secondary and tertiary healthcare levels will send, upon discharge, discharge letters for all treated cancer patients to the referring physician and to the patient's home. Discharge letters contain data on the diagnosis, procedures, therapies, including the recommendations for the patient and their personal physician.

Oncology centres at the secondary and tertiary levels organise an accessible counselling service (phone, e-mail) for personal/family physicians, in the event that they have additional questions related to treatment complications. Responsible institutions: Institute of Oncology Ljubljana and oncology centres.

- **Measure 1**: By the end of 2017, the PB for oncology and family medicine will process the mandatory dataset for a standardised letter of discharge to be submitted for consideration to the Expert Council of the Institute of Oncology Ljubljana.
- **Measure 2**: To record in the letter of discharge the contact numbers/e-mail addresses required for the consultation of the family physician.
- **Measure 3**: To include the standardised letter of discharge in the e-Zdravje system as soon as it is established.

#### 2. Secondary and tertiary healthcare

#### a. Diagnosis

#### a. Cell-tissue diagnostics and molecular diagnostics

This type of diagnostics is the only one that enables the diagnosis of a malignant tumour and the precise definition of the cancer type; furthermore, the examination of the surgical sample contributes to a more detailed definition of the stage, the radicality of the procedure and to numerous prognostic and predictive factors, all of which affect the selection and the sequence of treatment methods.

The specific objectives for the field of cell-tissue and molecular diagnostics are:

**Objective 1**: To establish a uniform work protocol for pathologists dealing with diagnostics in the field of oncology within secundary healthcare level by the end of 2018. Responsible institutions: Institute of Oncology Ljubljana and secondary-level institutions.

- Measure 1: To draft a work protocol (SOP standard operating procedures) for pathologists dealing with diagnostics at secondary-level hospitals by the end of 2017. The work protocol must include special protocols for those secondary-level hospitals that operate within the tumour diagnostic process in areas for which the hospital also carries out diagnostic imaging and surgical treatments. Secondary-level institutions must consult with a tertiary centre. Responsible institution: Institute of Oncology Ljubljana
- Measure 2: To carry out a pilot implementation of work protocols (SOP standard operating procedures) for pathologists dealing with diagnostics in all secondary-level hospitals by mid-2018. Responsible persons: professional directors of secondary institutions

**Objective 2:** To establish frozen tissue tumour banks by 2021 in all tertiary-level oncology centres (Institute of Oncology Ljubljana, Maribor University Medical Centre, Ljubljana University Medical Centre, Institute of Pathology of the Faculty of Medicine, the Golnik Clinic), and to use the LIS system (laboratory information system) with a standardised test result, including molecular targets defined in the Guidelines. Responsible institution: Institute of Oncology Ljubljana in cooperation with tertiary-level oncology centres.

- **Measure 1**: A responsible tertiary-level institution prepares the project for the laboratory information centre (LIS), including the timeline and the definition of the tasks of the project group, at centres for the histopathological testing of tumours by mid-2018. Responsible institution: to be determined by the NCCP Medical Council by mid-2017.
- **Measure 2**: Determining additional standards for acquiring the status of a centre for the histopathological testing of tumours by the end of 2018, as included in the Rules on the Operation of Medical Laboratories. Responsible institution: The Ministry for Health.
- **Measure 3**: Tertiary-level institutions for the histopathological testing of tumours will use the LIS system by the end of 2018. Reponsible institutions/persons: management of institutions at the tertiary healthcare level.
- **Measure 4**: Expert and procedural confirmation and implementation of the standardised report for the histopathological testing of tumours by the end of 2019. Responsible institution: Institute of Oncology Ljubljana
- **Measure 5**: Four oncology centres at the tertiary level will establish a frozen tissue tumour bank by the end of 2020, in accordance with the latest international standards. Responsible institutions: the management of the pathology departments of the four tertiary-level centres.
- **Measure 6**: The results of molecular genetic testing and other testing of prognostic and predictive factors on tumour tissue must be a mandatory part of standardised pathological report. This also applies in cases when molecular genetic testing is conducted subsequently. The set of required additional (molecular) tests, which are a part of the standardised test results, is checked and, if necessary, supplemented once a year. Deadline: 2017. Responsible institution: Institute of Oncology Ljubljana, Institute of Pathology of the Faculty of Medicine of the University of Ljubljana, the PB for pathology and forensic medicine, the PB for oncology, and the Golnik Clinic.

The specific objectives in the field of cytopathological diagnostics are:

**Objective 1:** To devise a clinical pathway for further diagnostics (referral) in the event of a suspicious or positive cytopathological diagnosis in lymphoma and malignant soft tissue tumours by the end of 2017. Responsible institution: the lymphoma and sarcoma team at the Institute of Oncology Ljubljana in cooperation with the Department of Cytopathology.

**Objective 2:** To establish a single database for all cytopathological and histopathological test results of Slovenian patients (LIS), to which all Slovenian pathologists would have access and which would contribute to a quicker cell-tissue diagnostics. Responsible institution: Institute of Oncology Ljubljana in cooperation with the Institute of Pathology of the Faculty of Medicine in Ljubljana (see Objective 2 in the chapter *Cell-tissue diagnostics*).

**Objective 3:** The Department of Cytopathology at the Slovenian Medical Association, in cooperation with all cytopathologists, continues its activities for a uniform assessment of cytological samples in fields in which classifications are already established: reporting

thyroid cytopathology results according to Bethesda, the Paris system for reporting urinary cytopathology; classifications for assessing cytological samples of the hepatobiliary tract and the pancreas by 2019. Responsible institution: Department of Cytopathology, Institute of Oncology Ljubljana.

**Objective 4**: To increase the number of qualified specialists based on a situation analysis in order to suitably manage the cancer issue in the country in the field of pathology. At least two pathologists employed in each pathology department by 2020; these pathologists must have suitable knowledge in the fields dealt with in laboratories for cytopathological diagnostics. The objective is fulfilled either by additionally training the already employed pathologists or within the specialisation programme for pathology. Responsible institutions: medical specialisation coordinators, tertiary and secondary healthcare institutions where cytopathological diagnostics is carried out.

The additional specific objectives for the field of molecular diagnostics are in *Appendix 1* to this document.

#### b. Diagnostic imaging

The role of diagnostic imaging in oncological healthcare is mainly to determine the locoregional and systemic spread of the disease and to monitor therapeutic effects. This includes radiology (x-ray, ultrasound, CT, MRI), nuclear medical (scintigraphy), and combined (PET-CT) imaging.

**Objective 1:** To establish a teleradiology system by mid-2019, in which all secondary and tertiary healthcare institutions in the field of diagnostic imaging in the Republic of Slovenia are included. Responsible institution: NIPH in cooperation with the PB for radiology and the Institute of Oncology Ljubljana.

- **Measure 1**: To appoint a responsible institution by the end of 2017 and its tasks related to managing the teleradiology project, including a situation analysis and the preparation of the project time-line and financial assessment. Responsible institution: NIPH
- **Measure 2**: Preparing and implementing an information system for establishing teleradiology by mid-2018. Responsible institution: NIPH
- **Measure 3**: Launching teleradiology in tertiary institutions by the end of 2018. Responsible institution: NIPH
- **Measure 4**: Including the teleradiology system for secondary institutions by mid-2019. Responsible institution: NIPH in cooperation with the Ministry of Health and public healthcare institutions.
- **Measure 5**: Standardising diagnostic devices within and between centres by gradually harmonising imaging devices (PET/CT, MRI, CT). Responsible institution: NIPH

**Objective 2**: To use the standardised protocol for the entire field of diagnostic imaging for cancer at secondary and tertiary healthcare institutions by the end of 2018. Responsible institution: The Institute of Oncology Ljubljana in cooperation with the PB for radiology.

- **Measure 1**: To prepare a standardised diagnostic imaging protocol by laying down minimum standards for the field of diagnostic testing and organic systems for cancer patients by mid-2017. Responsible institution: Institute of Oncology Ljubljana in cooperation with external associates.
- **Measure 2**: Confirming the standardised protocol by the competent PB by the end of 2017. Responsible institution: The PB for radiology.
- **Measure 3**: Introducing the standardised protocol in secondary and tertiary healthcare institutions by mid-2018. Responsible institutions: secondary and tertiary institutions.

**Objective 3**: Reducing waiting periods for patients diagnosed with a malignant disease for diagnostic imaging (CT, MRI) to a period accepted by experts by the end of 2020. Responsible institution: Institute of Oncology Ljubljana in cooperation with the Ministry of Health and the Health Insurance Institute of Slovenia.

- **Measure 1**: Preparing a situation analysis on waiting periods of diagnostic imaging for selected cancer patients, mid-2018. Responsible institutions: The Institute of Oncology Ljubljana and the Health Insurance Institute of Slovenia.
- **Measure 2**: Preparing human resources and organisational measures for reducing the waiting periods of cancer patients based on the situation analysis by the end of 2018. Responsible institutions: The Institute of Oncology Ljubljana and the Ministry of Health.
- **Measure 3**: Introducing priority measures for reducing waiting periods by the end of 2019, in order to reac anl acceptable level by the end of 2020. Responsible institution: Institute of Oncology Ljubljana

#### c. Endoscopic diagnostics

Bronchoscopic diagnostics can be performed only at centres that have the know-how and the technology to access peripheral lesions and to carry out staging procedures for chest tumours. When diagnosing central tumours, a centre must be able to take biopsy material for diagnosis and molecular markers in more than 90% of procedures. At least five biopsies per procedure must be performed.

**Objective 1:** To publish, by the end of 2017, guidelines for the field of endoscopic diagnostics and the criteria for establishing a system for suitable referrals of patients and the timely access to diagnostics on the website <u>www.dpor.si</u>. Responsible institution: The Golnik Clinic.

• **Measure 1**: Preparing guidelines by mid-2017 and submitting them to be reviewed by the NCCP Medical Council by the end of 2017. Responsible institution: experts at the Golnik Clinic.

**Objective 2:** To establish a network of diagnostics centres for lung cancer and thoracic cancer based on know-how, competences, and equipment by the end of 2019. Responsible institution: The Golnik Clinic in cooperation with other centres.

- **Measure 1**: Laying down criteria by the end of 2018 for such centres, which are defined on two levels: the level of diagnostic bronchoscopy and the level of expert intervention and diagnostic endoscopy of the respiratory system, whereby the proposal for such centres is confirmed by the NCCP Supervisory Council. Responsible institutions: PB and the NCCP Supervisory Council.
- **Measure 2**: Developing standard endoscopic treatment procedures (SOP's) by the end of 2018 for patients who are suspected of having lung cancer. Responsible institution: The Golnik Clinic.
- **Measure 3**: Introducing the implementation of the endoscopic diagnostic programme at verified oncology centres by the end of 2019. Responsible institutions: Ministry of Health and the Health Insurance Institute of Slovenia (ZZZS)

**Objective 3:** To establish a system for controlling the quality of the work of secondary and tertiary centres covering the field of endoscopic diagnostics by the end of 2020. Responsible institution: The Golnik Clinic in cooperation with the Health Insurance Institute of Slovenia.

 Measures for fulfilling the objective: Devising clinical pathways for outpatient diagnostics, day hospitals, and the hospitalisation of patients for the purpose of diagnostics for both levels, and an accounting model. Creating a dataset for the report on work quality and scope, which is provided to the NCCP Medical Council and the NCCP Supervisory Council once a year.

**Objective 4:** To introduce standardised education courses for all levels of respiratory system endoscopy with suitable qualification tests by the end of 2020. Responsible institution: The Golnik Clinic.

**Gastroenterological endoscopic diagnostics**, i.e. the diagnostics related to cancer of the digestive system, is carried out by numerous specialists, mainly at the secondary healthcare level, according to established expert diagnostics recommendations. The objective of diagnostics is to define and histologically confirm a tumour. It is carried out by gastroenterologists, internists focusing on gastroenterology, and surgeons.

**Objective 1**: To provide access to endoscopic diagnosisand treatment at an equal expert level to all Slovenians who are suspected of having cancer; this is to be provided at the secondary and tertiary healthcare levels by the end of 2019.

- Measure 1: Endoscopic diagnostics esophagogastroduodenoscopy and colonoscopy are carried out at the secondary and tertiary healthcare levels and in centres, related to which the quality of the performance of endoscopic diagnostics is controlled. It is only carried out by trained specialists. Deadline: by 2018. Responsible institution: Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine in cooperation with the Slovenian Society for Gastroenterology.
- Measure 2: Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic papillotomy and endoscopic ultrasound tests are carried out at the tertiary level and in those secondary-level centres where more than 200 ERCP or EUS tests are done per year. Deadline: by 2018. Responsible institution: Ljubljana University Medical Centre Clinic of Gastroenterological Internal Medicine

- Measure 3: Endoscopic ultrasound diagnostics with biopsies is carried out at the secondary and tertiary healthcare levels, where suitable cytohistological diagnostics is provided (see the objectives and measures in the chapter titled Cytopathology). Responsible institution: Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine
- **Measure 4**: Enteroscopy and holedohoscopy may be carried out in one tertiary centre, where special endoscopy equipment is provided. Deadline: by 2019. Responsible institution: Ljubljana University Medical Centre Surgical Gastroenterological Clinic
- **Measure 5**: Laparoscopic gastroenterological diagnostics is carried out by surgeons at secondary/tertiary centres, where suitable cytohistological diagnostics is provided (see the objectives and measures in the chapter Cytopathology). Responsible institution: Ljubljana University Medical Centre Surgical Gastroenterological Clinic
- **Measure 6**: All patients with advanced precancerous lesions with a significant risk of cancer or patients with early-stage cancer discovered after an endoscopic procedure was carried out must be presented to the multidisciplinary consultation team at a tertiary or secondary-level oncology centre by 2018. Responsible institution: Ljubljana University Medical Centre Clinic of Gastroenterological Internal Medicine

**Objective 2:** Endoscopic treatment of cancer of the digestive tract is performed in accordance with adopted guidelines posted on <u>www.dpor.si</u> by 2018. Responsible institution: Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine in cooperation with the Ljubljana University Medical Centre – Surgical Gastroenterological Clinic and the Slovenian Society for Gastroenterology.

- Measure 1: In patients for whom early-stage cancer was discovered and removed during an endoscopic diagnostic procedure, a multidisciplinary treatment at a tertiary centre, where the decision on further treatment will be reached, is necessary. The treatment may be carried out at secondary and tertiary healthcare levels. Deadline: by 2018. Responsible institution: The Slovenian Society For Gastroenterology in cooperation with the Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine and the Ljubljana University Medical Centre – Surgical Gastroenterological Clinic.
- Measure 2: The elective endoscopic treatment of the early-stage cancers of the digestive tract and the removal of large precancerous lesions can only be carried out by appropriately trained specialists. Deadline: 2019. Responsible institutions: The Slovenian Society for Gastroenterology in cooperation with the Ljubljana University Medical Centre Clinic of Gastroenterological Internal Medicine and the Ljubljana University Medical Centre Surgical Gastroenterological Clinic.
- Measure 3: The endoscopic radiofrequency ablation following endoscopic procedures can only be carried out at a tertiary-level oncology centre. Deadline: 2018. Responsible institution: Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine in cooperation with the Ljubljana University Medical Centre – Surgical Gastroenterological Clinic.
- Measure 4: The endoscopic palliative treatment of patients with an advanced cancer of the digestive tract is carried out by appropriately trained specialists at the secondary and tertiary healthcare levels. Deadline: 2018. Responsible institution: Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine in

cooperation with the Ljubljana University Medical Centre – Surgical Gastroenterological Clinic.

#### 5.2.3.2.2. Treatment

Initial treatment is most essential for the successful treatment of cancer patients. This treatment must be planned by a multidisciplinary team, which must keep standardised documentation on its decisions.

#### a. Surgical treatment

An oncological surgeon is a member of a multidisciplinary team, in which he works together with experts from complementary fields (diagnostics, radiation therapist/oncologist, medical oncologist) on all aspects of treating cancer patients – prevention, diagnostics, treatment, monitoring, and palliative care. In addition to special knowledge concerning surgical procedures, surgical oncologists must also know numerous diagnostic, clinical, support, reconstructive, and rehabilitation medical procedures that provide patients with the best possible quality of survival.

The surgical objectives, which complement the horizontal objectives within diagnostics and treatment, are:

**Objective 1:** To establish by the end of 2018 a network of fully operational oncology centres for the surgical treatment of specific cancer types, which only includes those centres that follow the guidelines and meet the criteria proposed in the <u>NCCP</u>  $2010-2015^{12}$ . Responsible institution: The Institute of Oncology Ljubljana in cooperation with oncology centres at the secondary and tertiary healthcare levels.

 Measure 1: Based on the measures proposed in the NCCP 2010–2015 and the data from the Cancer Registry of the Republic of Slovenia, the NCCP Medical Council prepares a proposal for a network of oncology centres for the surgical treatment of cancer, which is then confirmed by the PB for oncology and the NCCP Supervisory Council.

**Objective 2:** To have quality control performed in all secondary and tertiary healthcare institutions in Slovenia operating in the field of oncology by 2020 (as laid down in chapter 7.2.): Responsible institutions: Institute of Oncology Ljubljana (Cancer Registry), NCCP Medical Council, and the NCCP Supervisory Council.

• **Measure 1**: The control of systemic quality indicators for surgical activities will also be performed by the Cancer Registry; Eureka indicators will be used for gastroenterology.

<sup>&</sup>lt;sup>12</sup> The criteria for a network of oncology activities as defined in the NCCP 2010–2015 are available at the following link: http://www.dpor.si/?page\_id=28.

#### b. Systemic treatment

In principle, systemic cancer treatment affects the entire organism of a patient. Systemic cancer treatment includes cytostatic treatment or chemotherapy, hormonal therapy, targeted therapy, and medications that affect the immune system.

Due to the tremendous increasesystemic treatment possibilities, this treatments are not performed only in tertiary institutions, but a part of the treatments are now also transferred to oncology centres at the secondary and tertiary healthcare levels (Ljubljana University Medical Centre – Clinic of Gastroenterological Internal Medicine, Maribor University Medical Centre, the Golnik Clinic, Celje General Hospital, Nova Gorica General Hospital, Slovenj Gradec General Hospital, Izola General Hospital).

**Objective 1**: To include all public healthcare institutions which successfully underwent the verification of quality standards for oncological activities and that only treat particular cancer types into the network of oncology centres for systemic treatment by the end of 2019. Responsible institution: The NCCP Medical Council in cooperation with Section of Medical Oncology of the Slovene Medical association and the Department of Medical Oncologyat the Institute of Oncology Ljubljana.

- **Measure 1**: To perform the situation analysis on the incidence of frequent cancer types by regions in Slovenia by the end of 2017. Responsible institution: The Cancer Registry of the Republic of Slovenia.
- Measure 2: Based on the situation analysis concerning medical oncologists (see Objective 2, Measure 1) and the situation analysis concerning frequent cancer types by regions in Slovenia, a revision of the plan for a network of oncology centres for systemic treatment is to be carried out by mid-2018. Oncology quality standards, including quality standards for oncology pharmaceutical activities, are a part of the revised plan. Responsible institution: The Section of Medical Oncology at the Slovenian Medical Association and the Department of Medical Oncology at the Institute of Oncology Ljubljana in cooperation with clinical pharmacologists.

The specific objectives for the field of pharmaceutical oncological treatment are listed in *Appendix 2*.

**Objective 2**: To provide additional employment opportunities for all qualified medical oncologists<sup>13</sup> by 2020 at the Institute of Oncology Ljubljana and in oncology centres at the secondary and tertiary healthcare levels that are included in the implementation of systemic cancer treatment Responsible institution: The Ministry of Health and the Health Insurance Institute of Slovenia in cooperation with the management of tertiary and secondary-level institutions.

• **Measure 1**: Based on the situation analysis, a revised plan for human resources in the field of medical oncology for the Republic of Slovenia is to be drafted and revised at the

<sup>&</sup>lt;sup>13</sup> Medical oncologists are those specialists that spend at least 80% of their working hours carrying out systemic cancer treatment.

Medical Chamber of Slovenia by the end of 2017. Responsible institutions: The Ministry of Health and the Health Insurance Institute of Slovenia in cooperation with the medical specialisation coordinator for medical oncology, the Section of Medical Oncology at the Slovenian Medical Association and the Department of Medical Oncology Institute of Oncology Ljubljana.

• **Measure 2**: By the end of 2018, an additional 10 specialist medical oncologists will be employed in secondary/tertiary healthcare institutions where systemic cancer treatment is performed. Responsible institutions/persons: management of secondary centres.

#### c. Radiotherapy

Radiotherapy is an effective method for local cancer therapy, either with the purpose of curing the disease or for relieving its symptoms. It encompasses teleradiotherapy (TRT) and brachytherapy (BRT), both of which require special equipment installed in special premises that meet legislative requirements for the protection from ionising radiation.

**Objective 1:** To ensure access to radiotherapy according to the European recommendations for cancer patients by the end of 2020. Responsible institution: Institute of Oncology Ljubljana in cooperation with the management of the Maribor University Medical Centre, the Health Insurance Institute of Slovenia, and the Ministry of Health.

- **Measure 1**: The Radiotherapy Department at the Maribor University Medical Centre will be fully operational by the end of 2020 (both linear accelerators in two shifts) and it will take over the task of performing palliative radiation of all tumour sites and the radical radiation of breast, colorectal, and lung cancer (pursuant to technical and professional capabilities) for patients from north-eastern Slovenia. Responsible institution: Maribor University Medical Centre in cooperation with the Institute of Oncology Ljubljana.
- **Measure 2**: Based on a situation analysis, the financial resources for radiation devices, which will ensure the achievement of Objective 1, will be provided by the end of 2020. Responsible institutions: The Ministry of Health and the management of the Institute of Oncology Ljubljana and the Maribor University Medical Centre.
- Measure 3: Based on a situation analysis, the proposal for human resources teams and organisational measures at both radiotherapy centres will be prepared by the end of 2019. Responsible institutions: Ministry of Health, the Health Insurance Institute of Slovenia, the management of the Institute of Oncology Ljubljana, and the management of the Maribor University Medical Centre.
- **Measure 4:** A stable source of funding must be ensured and real depreciation costs, hardware and software maintenance costs and human resource costs must be taken into consideration. Responsible institutions: Ministry of Health, the management of the Institute of Oncology Ljubljana, and the management of the Maribor University Medical Centre.

**Objective 2:** To establish a European reference radiotherapy centre at the Institute of Oncology Ljubljana by mid-2018. Responsible institution: Institute of Oncology Ljubljana

• **Measure 1**: A comprehensive protocol for a radiotherapy reference centre, including work quality standards, the devising of professional guidelines, an education plan and a

plan for implementing professional supervision<sup>14</sup>, will be prepared by the end of 2017. Responsible institution: Institute of Oncology Ljubljana

• **Measure 2**: The PB for oncology will be considering the protocol for a reference radiotherapy centre by mid-2018. Responsible institution: Institute of Oncology Ljubljana

#### d. Nutritional support

Nutrition is a key field in adjuvant therapy in oncology. Using a suitable diet adjusted to individual patient's metabolism during the disease and its treatment is of extreme importance. The findings from this medical field, supported by evidence, have shown that the best solution for an effective nutritional therapy is a multidisciplinary approacht. Malnutrition can be considerably decreased by means of the suitable nutritional support of hospitalised patients and patients receiving outpatient care.

**Objective 1:** To establish the nutritional screening, consultation, malnutrition monitoring, and nutritional support of cancer patients in oncology centres at the secondary and tertiary healthcare levels by the end of 2020. Responsible institution: Institute of Oncology Ljubljana in cooperation with secondary and tertiary institutions.

- Measure 1: The measure related to the screening and consultation of cancer patients in the field of nutritional risk will be established and tested for all patients at the Institute of Oncology Ljubljana by the end of 2017. Responsible institutions: Department of Clinical Nutrition and the Medical Director of the Institute of Oncology Ljubljana.
- **Measure 2**: The remaining oncology centres at the secondary and tertiary levels treating cancer patients will be gradually included in the screening for nutritional support by the end of 2020, at the same time that nutritional consultation centres are established. Responsible institution: Department of Clinical Nutrition of the Institute of Oncology Ljubljana and the NCCP Medical Council and the management of oncology centres.
- **Measure 3**: In accordance with the clinical pathway for treating metabolic states at the primary level, it is reasonable to also include cancer patients in nutritional counselling. The situation at the primary level is to be checked and coordinated by the end of 2019.

#### e. Genetic counselling

In 25 to 30 percent of cancer patients, a positive family history related to more frequent cancer incidence is discovered. Approximately one third of cancer patients with a positive family history have what is known as a hereditary form of cancer. Today we are familiar with multiple genes that cause various types of hereditary cancer. Because it is common for hereditary cancers that multiple family members become ill (positive family history), oncological genetic counselling should be undertaken for patients and their healthy family members burdened with cancer. In Slovenia, there is currently a well-organised genetic counselling service and testing. The following cancers are most frequently tested: hereditary breast and ovarian cancer, hereditary non-polyposis colorectal cancer, familial adenomatous polyposis colorectal cancer, hereditary malignant melanoma, and medullary

<sup>&</sup>lt;sup>14</sup> Work quality standards have already been laid down, and professional guidelines, radiation protocols, and an education programme for physicians and medical physicists have already been devised. However, a plan for educating radiation engineers and nurses and for implementing professional supervision must still be devised.

thyroid cancer in the framework of multiple endocrine neoplasia type II (MEN II). Other, rarer forms of hereditary cancer are also treated within oncological genetic counselling and testing. Patients undergo a genetic consultation within a multidisciplinary team (MDT) prior to testing and after testing, as well as a genetic test; depending on the testing results, the MDT counsels patients and prepares and carries out prevention measures (screening for people with high risk of cancer).

**Objective 1**: For all reference outpatient clinics (already operating reference clinics within primary healthcare) in the Republic of Slovenia to have clear instructions by 2019 for referring patients for oncological genetic counselling and to use a screening survey for identifying those individuals who may come from families with hereditary syndromes that include cancer. Responsible institution: Institute of Oncology Ljubljana

• **Measure 1:** Referrral instructions and a proposal for a screening survey for selected cancer types and hereditary syndromes that include breast, thyroid, colon cancer and malignant melanoma by the end of 2017. Responsible institution: Institute of Oncology Ljubljana

• **Measure 2**: The Republic of Slovenia National Medical Ethics Committee will review and confirm by mid-2018 the screening survey and instructions for referring patients in this field. The Council of Reference Clinics will adopt the screening survey and the instructions for referring patients. Responsible institution: The Institute of Oncology Ljubljana in cooperation with the Republic of Slovenia National Medical Ethics Committee and the Council of Reference Clinics.

**Objective 2:** Oncological genetic counselling at a selected tertiary institution become one of the mandatory elements of medical specialisations for all specialising physicians in the field of genetics, gynaecology, oncology, and family medicine in the Republic of Slovenia by 2020. Responsible institution: The Institute of Oncology Ljubljana in cooperation with the Medical Chamber of Slovenia and Coordinators of relevant specialities.

• **Measure 1**: A proposal of a mandatory curriculum for selected medical specialist trainees who will perform a part of their specialist training in the field of oncogenetics will be drafted by the end of 2017. Responsible institution: Institute of Oncology Ljubljana

• **Measure 2**: The Medical Chamber of Slovenia will review and confirm the proposed changes to the curriculums of specialist trainings by the end of 2018. Responsible institutions: coordinators of proposed specialist trainings, the Medical Chamber of Slovenia.

#### f. Nursing

Oncological nursing is one of the most important parts of the healthcare system. The number of patients treated at oncology centres at secondary and tertiary healthcare levels is increasing, and hospital stays are short. Treatment is more and more frequently carried out in outpatient clinics with increasing amounts of oral medication administered.

**Objective 1**: To have the Institute of Oncology Ljubljana receive the status of a reference oncology nursing centre by the end of 2019. Prior to this, guidelines for this field must be drafted and posted on <u>www.dpor.si</u>; quality control for oncological nursing must be implemented at a national level. Responsible institution: Institute of Oncology Ljubljana

- **Measure 1**: The Institute of Oncology Ljubljana will prepare a proposal for the guidelines and indicators for the quality control of oncological nursing by mid-2017.
- **Measure 2**: Professional Group of Nurses at the Nurses and Midwives Association of Slovenia (ZZBZ) will confirm the guidelines for oncological nursing by the end of 2017, which will enter into force in all oncology centres by mid-2018 and be published on <u>www.dpor.si</u>.
- **Measure 3**: The report, including the quality indicators for oncological nursing, will be drafted by mid-2019 for all secondary and tertiary oncology centres. Responsible institution: Professional Group of Nursesat the Nurses and Midwives Association of Slovenia.

## 5.2.4. Comprehensive rehabilitation

The treatment outcome for a large number of cancers is improving, so it is becoming increasingly more important to ensure a high-quality of life for all cancer patients. The number of people surviving cancer is increasing, but they are hindered by the consequences of the disease and/or its treatment in everyday life. It is reasonable to take rehabilitation measures from the beginning of treatment to the end of life. The strategic objective for the field of comprehensive rehabilitation, which must be defined in even greater detail at a national level and then implemented, is: **"To ensure a high-quality of life to cancer patients by providing comprehensive and timely rehabilitation."** 

The specific objectives for comprehensive rehabilitation are:

**Objective 1**: To prepare guidelines and clinical pathways, coordinate providers in the network of comprehensive rehabilitation<sup>15</sup>, carry out quality control, educate human resources, and inform expert and other segments of the public on the significance of rehabilitation by mid-2018, within the framework of an action plan for the comprehensive rehabilitation of cancer patients. Responsible institution: The Ministry of Health in cooperation with the Institute of Oncology Ljubljana and the University Rehabilitation Institute of the Republic of Slovenia SOČA.

- **Measure 1**: One month after adopting the NCCP 2017–2021, the Ministry of Health will appoint the members of a professional group for comprehensive rehabilitation and one coordinator for this field, and it will also define their responsibilities, competencies, and duties. The professional group for comprehensive rehabilitation will consist of a maximum of 10 members.
- **Measure 2**: The professional group for comprehensive rehabilitation will draft *the Action Plan for Comprehensive Rehabilitation in the Republic of Slovenia 2017–2018* by the end of 2017, which will also contain the responsibilities and duties of the manager, the responsibilities and duties of the providers, and the responsibilities and duties of other programme management bodies, the guidelines and clinical pathways for comprehensive rehabilitation for five key fields or diagnoses, the implementation of quality control, the education of human resources, and the recommendation of the establishment of comprehensive rehabilitation in the Republic of Slovenia.

<sup>&</sup>lt;sup>15</sup> The network of comprehensive rehabilitation is a systemic group of healthcare institutions at the vertical and horizontal levels.

• **Measure 3**: On behalf of the professional group for comprehensive rehabilitation, the manager will prepare an application by the end of 2018 for the medical council based on *the Action Plan for Comprehensive Rehabilitation in the Republic of Slovenia* to ensure the funding for a pilot project in 2019 and for the remaining areas of comprehensive rehabilitation in the years to come.

**Objective 2:** Patients will begin entering the network of comprehensive rehabilitation in 2019, within the framework of a pilot project that includes all healthcare levels, whereby the majority of cancer patients will undergo comprehensive rehabilitation by the end of 2021. Responsible institutions: The University Rehabilitation Institute of the Republic of Slovenia SOČA and the Institute of Oncology Ljubljana.

- **Measure 1**: The comprehensive rehabilitation pilot project will be carried out in 2019 with the purpose of testing the access points for monitoring and coordinating comprehensive rehabilitation, the operability of the established network, so that within the pilot project rehabilitation teams form, questionnaires for screeningas well as the evaluation of the *Action Plan for Comprehensive Rehabilitation in the Republic of Slovenia* in practice, including its financial sustainability. The implementation of the pilot project is the basis for performing a situation analysis and the groundwork for the professional education of human resources. Responsible institution: the manager with the working group of comprehensive rehabilitation.
- Measure 2: If additional human resources are provided, the manager of comprehensive rehabilitation will systematically educate human resources as of 2019; these human resources will then perform comprehensive rehabilitation in the Republic of Slovenia at all healthcare levels (PRM, clinical psychologists, logopedists, occupational therapists, psychiatrists, and others).
- **Measure 3**: Based on the pilot project records, a revised proposal of *the Action Plan for Comprehensive Rehabilitation 2020–2021* will be submitted by the end of 2019, in which the competencies of providers and the professional guidelines for the comprehensive rehabilitation in Slovenia for cancer patients and other elements defined in *the Action Plan for Comprehensive Rehabilitation 2017–2018* will be defined and upgraded.

## 5.2.5. Palliative care

Palliative care is the care for patients with chronic, terminal, and progressive diseases. It is defined as a complex approach to alleviating physical and psychological symptoms of a progressive disease from the perspective of the patient's mental and spiritual experience in the social environment in which the patient lives alone or with their loved ones. It is intended to provide a high quality of life by taking into consideration the patient's values. It also integrates their loved ones, if they so wish, during the illness and the period of mourning.

The specific objectives in palliative care, which will be supported in greater detail by the *Action Plan of the National Programme of Palliative Care* by means of its measures, are:

**Objective 1:** In the revised Action Plan of the National Programme of Palliative Care, which will be confirmed by the Government of the Republic of Slovenia by the end of 2017, the

organisational and financial measures enabling the establishment of a palliative care network in Slovenia will be defined in at least three regional units of Slovenia by mid-2018 and in at least six regional units by the end of 2020.

**Objective 2:** To include a 50-hour educational course on palliative care in the medical specialisation programmes of all clinical specialist fields and of family medicine by the end of 2020, whereby education on palliative care for all healthcare workers performing palliative care will also be organised in all regions by 2020.

**Objective 3**: For all units in the palliative care network to undergo regular annual control as of the commencement of their operation, performed by the national coordinator in cooperation with regional coordinators of palliative care based on valid guidelines, which will be drafted by the end of 2017.

#### 5.2.6. Research

In order for progress to be made in cancer management, research and knowledge acquisition in all fields related to the management of this disease are required – from prevention, diagnostics, treatment, and rehabilitation to palliative care. The patients included in clinical studies have better chances of survival..

**Objective 1:** The harmonised legislation on research activities enabling additional research work to be carried out by healthcare workers employed full-time will enter into force by the end of 2019. Responsible institutions: Institute of Oncology and competent ministries.

• **Measure 1**: A proposal for harmonising the legislation on research and healthcare activities will be drafted by the end of 2018.

**Objective 2:** To establish a fund for financing oncology research at tertiary centres by the end of 2018. Responsible institutions: The Institute of Oncology Ljubljana and the management of oncology centres at the tertiary healthcare level.

• **Measure 1**: A legal framework for the operation of the fund, including the establishment of the management of the fund, adopting a code of ethical conduct, forms of donations of legal entities and persons, and activities for promoting the fund, will be devised by the end of 2017.

**Objective 3**: To include more than 10% of all cancer patients into clinical studies in oncology by the end of 2021. Responsible institution: The NCCP Medical Council.

• **Measure**: HR and organisational measures that are financially sustainable will be implemented in practice by the end of 2019, together with activities related to informing patients on the option to participate in clinical studies.

**Objective 4**: For oncology centres at the tertiary healthcare level to have a system for carrying out clinical studies established by the end of 2021. Responsible institutions/persons: the management of tertiary institutions.

**Objective 5:** For the Institute of Oncology Ljubljana to establish a system for carrying out phase 1/2 clinical studies in oncology by the end of 2021. Responsible institution: Institute of Oncology Ljubljana

- **Measure 1**: The management of a tertiary institution will devise a plan for carrying out clinical studies by planning resources and developing a time-line by mid-2018. Responsible institution: the management of the Institute of Oncology Ljubljana.
- **Measure 2**: Human resources for carrying out clinical studies will be educated at reference centres abroad by the end of 2019.
- **Measure 3**: The trial implementation of phase 1/2 clinical studies will begin in the first half of 2021.

## 5.2.7. Education

Considering that cancer is the number one cause of death for men and the number two cause of death for women in Slovenia, the education of human resources in healthcare is insufficient. In addition to the measures for the constant performance of educational courses for all human resources in healthcare in Slovenia, expanding the scope of education on cancer in all undergraduate and postgraduate study programmes would enable more knowledge regarding cancer and, as a result, better diagnostis and treatment of cancer patients.

**Objective 1**: To lay down by 2020 the areas of oncology that family physicians are required to master. Responsible institution: Chair of Family Medicine and Oncology, the Faculty of Medicine (University of Ljubljana)

• **Measure 1**: In agreement with the Chairt of Oncology and Family medicine of the Faculty of Medicine at the University of Ljubljana, and the coordinator of the medical specialisation in family medicine, the educational topics and competences in oncology for those specialising in family medicine will be reviewed. Responsible institution/person: Chairs of Oncology and family Medicine and the coordinator of the medical specialisation in family medicine.

**Objective 2**: To define by 2020 the percentage of mandatory credit points in oncology in the post-specialist education for physicians and other healthcare human resources. Responsible institution: all chambers of medical professions.

• **Measure 1**: In agreement with the chambers of medical professions, the percentage of mandatory credit points in oncology will be defined and the suitable rules will be amended/modified. Responsible institution/person: the NCCP coordinator for education in cooperation with the chambers of medical professions.

**Objective 3:** To review by 2020 the educational topics in oncology that are intended for healthcare workers and to suitably update them, especially those related to nursing and specialist clinical pharmacy. Responsible institution: all chambers of medical professions.

• **Measure 1:** Topics will be reviewed and proposals for updates will be drafted in cooperation with partners: nursing – the Faculty of Health Sciences Ljubljana, the Faculty of Health Care Jesenice, clinical pharmacy – Pharmaceutical Chamber of Slovenia.

• **Measure 2:** The review and confirmation of the proposed changes in curriculums.

The specific objectives in education related to genetic counselling, endoscopic diagnostics, and palliative care are listed above under each section.

## 5.2.8. Monitoring the burden of cancer

The basic indicators that describe the burden of cancer in a population are incidence, mortality, prevalence, and survival. All of this data serve as the starting point for estimating the success of primary and secondary prevention in oncology, diagnosti and, treatment, rehabilitation, and palliative care, and for planning the capacities and resources required to control cancer in all of these areas. The database of the Cancer Registry of the Republic of Slovenia (RRRS) is the source of data on incidence, prevalence, and survival. The RRRS is one of the oldest cancer population registers in Europe located. at the Institute of Oncology Ljubljana since 1950.

**Objective 1:** To establish by the end of 2019 active cancer registration at the RRRS or a data collection system enabling the preparation of ongoing, complete, and high-quality indicators on the cancer burden in the country (with a one-year delay). Active cancer registration must be incorporated within the e-Zdravje system. Responsible institution: Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana)

- Measure 1: The situation analysis and the financial assessments of the current method of processing and reporting data by oncology healthcare providers and their registration into the RRRS will be drafted by the end of 2017. Responsible institution: Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana)
- Measure 2: Based on a situation analysis and following the example of successful foreign and local practices, an action plan for reorganising the reporting and recording of data will be drafted by mid-2018, which will include a time-line for activities and a financial assessment of the required resources (human resources, equipment, premises). An active registration of cancer will be proposed, in which data will no longer be provided by oncological healthcare providers, but will be directly collected by the RRRS staff. In 2018, the action plan will be submitted to the NCCP Supervisory Council for review, to the Health Insurance Institute of Slovenia for the confirmation of project funding, and to oncological healthcare providers, so that the necessary formal and technical adjustments may be performed. Responsible institution: The Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana).
- Measure 3: A plan for active collection and registration of cancer patient data will be established by the end of 2019, whereby the first overview of full and high-quality population indicators related to the burden of cancer in Slovenia for the preceding year will be drafted by the end of 2020. Responsible institutions: The Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana) and the management of the Institute of Oncology Ljubljana

**Objective 2:** To establish clinical registries for the most frequent cancer types by the end of 2020 and to expand the dataset monitored by the Cancer Registry of the Republic of Slovenia (RRRS) for certain cancer types, so that indicators for evaluating the quality of the treatment of cancer patients can be prepared. Clinical registries are coordinated with the e-Zdravje system. Responsible institution: Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana)

- Measure 1: In addition to a plan for active registration, the RRRS will, by the end of 2018, submit for expert review to the NCCP Supervisory Council and to the Health Insurance Institute of Slovenia as the funding provider the action plan and the financial assessment of the costs related to establishing clinical registries. The plan will include particular cancer types and indicators, for which the quality of treatment in the diagnostics and treatment process will be monitored and assessed at a national level. Responsible institutions: The Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana) and professional teams for individual fields (Institute of Oncology Ljubljana, ).
- **Measure 2**: The resources (human resources, informational, spatial) at the RRRS will be suitably upgraded by the end of 2019, which will, together with the active registration, enable the launch of a pilot clinical register. The first annual patient treatment quality report concerning the patients included in the clinical registry will be drafted by the end of 2020. Responsible institutions: The Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana) and the management of the Institute of Oncology Ljubljana
- Measure 3: All clinical registers foreseen in the NCCP will be established by the end of 2020, whereby the RRRS resources (human resources, premises, equipment) that enable the preparation of all of the agreed upon indicators for evaluating the quality of cancer patient treatment will be suitably upgraded. Responsible institutions: The Cancer Registry of the Republic of Slovenia (Institute of Oncology Ljubljana) and the management of the Institute of Oncology Ljubljana

## 5.2.9. Supporting environment – information technology

In addition to the stated specific objectives in the NCCP 2017–2021, special attention will also be paid to the supporting environment for its implementation, specifically to **information technology** at the primary, secondary, and tertiary healthcare levels. Therefore, a provision applies to all of the specific objectives below, which stipulates that information technology is developed in accordance and within the e-Zdravje system for the purpose of pooling data on cancer patients while avoiding the construction of separate mutually incompatible information systems.

**Objective 1**: To harmonise by 2021 the information technology of the healthcare systems at the primary, secondary and tertiary healthcare levels in the field of oncology with the e-Zdravje platform, or to integrate it into this platform. Responsible institution: Ministry of Health in cooperation with NIPH.

• **Measure 1**: By the end of 2017, the Ministry of Health in cooperation with the NCCP Medical Council will appoint members of a working group in the field of information technology, who will draft an analysis of the current condition, verify and coordinate

NCCP projects in the field of information technologies and measures for their integration into the e-Zdravje platform by the end of 2018. Responsible institutions: The Ministry of Health, the NCCP Medical Council, and the NIPH.

# 6. Cooperation with patient representatives, nongovernmental organisations, and the civil society

The cooperation with patient representatives, non-governmental organisations, and the civil society is indispensable when developing and implementing the National Cancer Control Programme 2017–2021.

In Slovenia, there are numerous societies and associations that patients and the civil society can join with the aim of cooperating and participating in decision-making together with the health policy and healthcare providers for the purpose of better cancer control.

Their cooperation is important in fulfilling nearly all of the strategic and specific NCCP objectives and measures. To highlight a few:

- working in raising the awareness of cancer and sharing information related to cancer prevention or primary prevention,
- motivation for participating in screening programmes,
- working in the field of psychosocial assistance (self-help groups),
- including patients into clinical studies,
- forming patient councils and working with the management of public health institutions,
- cooperation in preparing or amending legislation,
- cooperation in the processes of educating the expert public and the general public,
- having representatives in programme management and monitoring structures and in numerous other fields.

By raising the awareness of and informing the Slovenian public regarding primary prevention as well as the significance of screening programmes and early cancer detection and the experience of cancer patients in the process of treatment and diagnostics, the civil society can contribute much to the fulfilment of the desired results within comprehensive cancer treatment.

# 7. Managing and monitoring the NCCP

By coordinating all Programme stakeholders, the National Cancer Control Programme 2017–2021 can improve comprehensive cancer treatment in the Republic of Slovenia. This section describes the competencies and responsibilities of NCCP 2017–2021 bodies, and the objectives and measures for managing and monitoring the Programme.

The objectives and measures for managing the NCCP 2017–2021 in the first year of operation are:

- The members of the NCCP Medical Council and the NCCP Supervisory Council are to be appointed and established by means of a Decision adopted by the Ministry of Health within one month of the NCCP 2017–2021 being adopted by the Government of the Republic of Slovenia.
- The communication plan for circulating and informing the interested expert and general public on the Programme will be confirmed by the NCCP Medical Council by the end of 2017.

## 7.1. Bodies of the NCCP

## NCCP Supervisory Council:

- On an annual basis, it supervises the fulfilment of the strategic and specific objectives of the Programme.
- It confirms the oncology centre selection criteria and confirms oncology centres in the networks related to individual objectives of the Programme.
- In the event of any deviations from the set objectives of the Programme in the Annual report takes measures to improve the fulfilment of these objectives . , it
- It confirms the head Programme coordinator and the members of the NCCP Medical Council.
- It consists of representatives of the Ministry of Health, the Health Institute of the Republic of Slovenia, NIPH, the Medical Director of the Institute of Oncology Ljubljana, a representative of the Cancer Registry of the Republic of Slovenia and of all oncology centres at the tertiary and secondary healthcare levels in networks, and representatives of primary healthcare and the civil society (at least three representatives).
- It meets at least once a year.
- It operates in accordance with the NCCP Medical Council Rules, which will be drafted by the end of 2017.

## THE NCCP Medical Council:

- It provides professional management and coordinates the implementation of the specific objectives of the Programme.
- It monitors the preparation and confirmation of guidelines by the PB for oncology or other suitable PB's for all areas included in the NCCP 2017–2021. It publishes the latest professional guidelines for all NCCP segments on <u>www.dpor.si</u>.
- It annually drafts a report for the NCCP Supervisory Council on the fulfilment of specific objectives, including the quality indicators related to Programme implementation.

- In the event that, in individual oncology centres, there are deviations from guidelines and quality indicators, it reports on this to the NCCP Supervisory Council.
- It consists of the head NCCP coordinator, the coordinators of the eight NCCP areas (primary prevention, secondary prevention, diagnostics and treatment, rehabilitation, palliative care, research, education, information technology), and a representative of the Cancer Registry of the Republic of Slovenia.
- If required, it also carries out activities related to having an overview of Programme funding.
- It meets every two months. It is led by the head coordinator of the NCCP 2017–2021.
- It operates in accordance with the NCCP Medical Council Rules, which will be drafted by the end of 2017.

#### NCCP COORDINATOR:

- The management, implementation, and the analysis of NCCP 2017–2021 indicator falls under the purview of the head Programme coordinator with a five-year mandate.
- Leading the Programme includes activities relating to Programme management (fulfilling strategic and specific objectives of the Programme) and comprehensive Programme communication (preparing and implementing the Programme communication strategy for comprehensively informing all stakeholders and managing the NCCP website).

#### NCCP REGIONAL COORDINATORS:

- Regional coordinators with a five-year mandate are responsible for implementing the eight individual Programme areas.
- Regional coordinators are appointed for: primary prevention, secondary prevention, diagnostics and treatment, comprehensive rehabilitation, palliative care, research, education, monitoring the burden of cancer, and information technology.
- Each regional coordinator is responsible for the fulfilment of the NCCP 2017–2021 objectives for the area, for which they were mandated.

## 7.2. Monitoring the Programme

To facilitate comprehensive NCCP 2017–2021 implementation, a suitable system for monitoring the fulfilment of strategic and some of the more significant specific objectives of the Programme will be provided. Below are the professional objectives and measures for the preparation of guidelines, establishment of networks, and implementation of Programme monitoring procedures.

#### GUIDELINES

Expert objective 1: To draft the expert guidelines of the primary and secondary prevention, diagnostics and treatment, comprehensive rehabilitation and palliative care of cancer patients by the end of 2018 and to post them on <u>www.dpor.si</u>.

• **Measure 1**: Individual expert teams are competent for developing expert guidelines for individual fields. These guidelines must be regularly revised every year pursuant to professional developments. The guidelines are confirmed by the competent PB's.

- **Measure 2**: Individual responsible institutions or persons for a selected field\* are responsible for the distribution and implementation of guidelines at all levels of the healthcare system.
- **Measure 3**: The officially valid guidelines for secondary prevention, diagnostics and treatment, comprehensive rehabilitation, and palliative care will be posted on the NCCP website by the end of 2018.

\*The responsible institutions or persons for preparing guidelines for individual NCCP areas are:

- <u>Primary prevention</u>: The National Institute of Public Health (NIPH) and a professional group for primary healthcare, the Institute of Oncology Ljubljana, the Ministry of Health (the Public Health Directorate), and other oncology centres.
- <u>Secondary prevention</u>: The Institute of Oncology Ljubljana for DORA and ZORA programmes, NIPH for the SVIT programme.
- <u>Diagnostics and treatment</u>: multidisciplinary teams at the Institute of Oncology Ljubljana and external expert associates.
- <u>Comprehensive rehabilitation:</u> University Rehabilitation Institute of the Republic of Slovenia Soča in cooperation with the Institute of Oncology Ljubljana.
- <u>Palliative care</u>: the working group for palliative care at the Ministry of Health.

#### TREATMENT NETWORKS

The purpose of networks is to fulfil the implementation of oncology healthcare services according to professional criteria of service quality pursuant to professional requirements, as defined by PB's based on the minimum number of treatments. Because in Slovenia diagnostis and treatment is practically carried out in the majority of Slovenian healthcare institutions, it will need to be defined, based on a new mode of operation of the Cancer Registry (see the objectives and measures in the chapter *Monitoring the burden of cancer*), which healthcare institutions meet this criteria and for which cancer types. A network for comprehensive rehabilitation (see the objectives and measures in chapter *Comprehensive rehabilitation*) and palliative care (see the Action Plan within the National Programme of Palliative Care) will be re-established, which providers will join based on the set professional criteria.

Expert objective 2: To include by the end of 2020 the public health institutions which, after being tested<sup>16</sup>, meet the required standards pursuant to the professional guidelines for carrying out the diagnostics and treatment of common cancers, comprehensive rehabilitation, and palliative care, and become oncology centres, are incorporated into the network of oncological healthcare services.

 Measure 1: Professional teams\* will prepare and chek criteria for oncology centres, based on which oncology centres will be able to join a network after a procedure that tests whether they meet these standards that will admitted to PB for oncology for confirmation by mid-2018.

<sup>&</sup>lt;sup>16</sup> The professional groups that will perform the testing will be determined later.

- **Measure 2:** Based on guidelines, RRRS report on performed treatments and PB opinion the NCCP Medical Council will prepare and submit to the NCCP Supervisory Council for confirmation a *Proposal for a Network of Providers in the Fields Related to Treating Common Cancer Types* by the end of 2018.<sup>17</sup>
- Measure 3: The testing of whether the criteria are being met by individual networks of oncology centres will be carried out by means of a new registration method of the Cancer Registry and will be a part of the annual report submitted to the NCCP Supervisory Council as of 2020.

\*The institutions responsible for preparing detailed measures, within which the required human resources, equipment, and premises are listed, for providers according to specific field are:

- <u>Diagnostics and treatment</u>: The Institute of Oncology Ljubljana in cooperation with external professionals in the field of diagnostics, a specific network for systemic, surgical, and radiotherapy treatment.
- <u>Comprehensive rehabilitation:</u> SOČA in cooperation with the Institute of Oncology Ljubljana.
- <u>Palliative care</u>: the working group for palliative care at the Ministry of Health.

#### PROCEDURES FOR MONITORING THE NCCP

It is foreseen that procedures for monitoring the Programme are to be carried out fully in networks related to diagnostics and treatment and partly in the field of comprehensive rehabilitation and palliative care, which will be determined in greater detail later.

Expert objective 3: For the Institute of Oncology Ljubljana and the oncology centres in the network for the diagnostics and treatment of common cancer types, comprehensive rehabilitation, and palliative care to be included in the procedures for monitoring the NCCP by the end of 2021.

• **Measure 1**: In its annual reports on the implementation of the NCCP, the NCCP Medical Council will report as of 2019 to the NCCP Supervisory Council and other interested Programme stakeholders on individual systemic and isolated deviations that were noticed in the healthcare system in the treatment of cancer patients.

The monitoring of the Programme is based on two procedures:

**a.** <u>The systemic monitoring of quality indicators</u> related to the treatment of common cancer types for the previous year is collected and published by the RRRS in clinical registries, which enable the short-term and long-term monitoring of indicators, such as the time from diagnosis to treatment, compliance with valid guidelines, the number of annual treatments of individual providers, treatment complications, survival, etc.

<sup>&</sup>lt;sup>17</sup> The implementation of this measure depends on the establishment of e-registration in the Cancer Registry of the Republic of Slovenia; see measures in chapter 5. 2.9 – Monitoring the burden of cancer.

**b.** <u>Multidisciplinary teams overviewcases of deviations related to the individual patients</u> that experience major deviations from the guidelines for diagnostics and treatment for the purpose of feedback and education, which will benefit both patients and providers.

The foreseen **procedures** on handling discovered deviations are:

#### (a) Systemic deviations

The providers in networks must carry out healthcare services pursuant to guidelines, whereby the criteria for joining a network must be met during the entire period in which these healthcare services are being rendered.

Professional teams are responsible for discovering and recording systemic deviations. In addition to fulfilling the objectives listed in chapter 5.2.8. herein, every year the RRRS drafts and submits to professional teams a report on quality indicators concerning each provider in a network for the previous year with regard to the cancers that are included in clinical registers.

If, taking into account the quality indicators, the achieved results show that there are deviations from the guidelines, the professional team must provide a recommendation for their elimination in its reports. These reports are submitted by the professional teams to all providers in a network, to the NCCP Medical Council and the NCCP Supervisory Council.

The providers concerning where it is discovered that there are deviations from the quality indicators are obliged to prepare an answer for the implementation of the recommendations within two months at the latest, and to submit these measures to the NCCP Medical Council and the NCCP Supervisory Council.

If the NCCP Supervisory Council deems that the planned measures for eliminating the deviations are not suitable, or if the deviations continue to occur, it has the option to inform the Medical Chamber and the Health Insurance Institute of Slovenia thereof.

#### (b) Deviations in specific cases

In individual cases where major deviations from the required professional guidelines are detected multidisciplinary teams initiate the procedure to inform the provider and his responsible legal representatives of public health institutions (i.e. the medical director of an institution) about these deviation.

The response to the deviations is intended to protect the rights of the patients to equal professional treatment and equal access to such treatment and to protect all of the healthcare workers and everyone else involved pursuant to Slovenian legislation. Furthermore, it is intended to provide constant education of the providers in a network, as the feedback also allows them to be included in the process of continuous education.

The procedure in practice will be as follows: When a physician, at an outpatient clinic or during a discussion within a consultation team, discovers a major deviation from professional guidelines in the treatment of a particular cancer patient, they shall inform the multidisciplinary team, which shall assess whether there is indeed such a deviation. If there

is, the physician must draft a brief report including a recommendation on suitable action to be taken and they shall also inform the medical director of their respective healthcare institution. The medical director is then competent to inform the provider and the medical director of the institution where the deviation occurred. The director must also inform the NCCP Medical Council.

In the event of any non-agreement between both healthcare institutions, the arbitrator will be the PB for oncology.

With the purpose of protecting the rights of patients and healthcare workers, these deviations must be included annually in the reports of the NCCP Medical Council and the NCCP Supervisory Council, namely in the form of summary data on such deviations.

The NCCP Supervisory Council has the option to inform the Medical Chamber about these deviations.

## 8. NCCP stakeholders

Numerous stakeholders will work on fulfilling NCCP 2017–2021 objectives and measures. Below are listed the activities of individual stakeholders, which were defined within the strategic and specific objectives of the Programme.

## 8.1. Ministry of Health

- Institution responsible for the NCCP, which provides strategic national and legal frameworks for ensuring that NCCP 2017–2021 objectives are met.
- One month after the Government of the Republic of Slovenia confirms the NCCP 2017–2021, it appoints members of the NCCP Medical Council and the NCCP Supervisory Council for a five-year mandate.
- It draws up and submits to the Government of the Republic of Slovenia the Legislation of databases in healthcare.

## 8.2. National Institute of Public Health (NIJZ)

- It carries out the tasks of a public service in the field of public health.
- With regard to immunisation against HPV, it aims to enhance the activities in the field of educating public employees and the target public.
- It manages the SVIT programme and is responsible for fulfilling the objectives of this screening programme.

## 8.3. Health Insurance Institute of Slovenia (ZZZS)

- It financially supports the implementation of the specific objectives and support measures of the NCCP 2017–2021 when the competent partners of the general agreement (GA) include them in the GA.
- It financially evaluates the specific objectives and measures, with regard to which new or extended programmes will be developed due to additional human resources and additional equipment.

## 8.4. Institute of Oncology Ljubljana (OIL)

- The only comprehensive oncology centre in the Republic of Slovenia.
- It enables the monitoring of the NCCP 2017–2021 performance based on the data provided by the Cancer Registry.
- It manages the DORA and ZORA screening programmes and is responsible for fulfilling the objectives of these programmes.
- It draws up diagnostics and treatment guidelines.
- With the help of its professional teams, the Institute is an important link in quality control.
- Furthermore, it is responsible for fulfilling the objectives within diagnostics and treatment, comprehensive rehabilitation, research and education, and the monitoring of the burden of cancer, as listed e for the fulfilment of particular objectives.

#### 8.5. Oncology centres at secondary and tertiary healthcare levels

- These carry out diagnostics and treatment in accordance with guidelines.
- They work on developing guidelines for diagnostics and treatment, comprehensive rehabilitation, and palliative care.
- Based on annual reports, they take measures in areas where the quality of care must be improved.

#### 8.6. Primary healthcare level

• They carry out activities in the field of primary and secondary prevention, diagnostics and treatment, comprehensive rehabilitation, and palliative care.

#### 8.7. Professional and occupational associations

• This group of stakeholders includes the Medical Chamber, the Slovenian Medical Association, the Pharmaceutical Chamber of Slovenia, the Nurses and Midwives Association of Slovenia, professional divisions, and other associations listed as the institutions responsible for individual objectives.

#### 8.8. Civil society

- It actively cooperates with the implementation of measures, and monitoring, managing, and supervising the NCCP 2017–2021.
- It cooperates with educating cancer patients and the general public on the importance of primary and secondary prevention and other NCCP 2017–2021 areas.

## 9. The financial assessment of measures

The Republic of Slovenia will finance the measures required for the fulfilment of the NCCP 2017–2021 objectives using the funds of the Health Insurance Institute of Slovenia and budgetary funds.

The funds for managing, monitoring, and implementing measures in primary cancer prevention and the prevention of noncommunicable (chronic) diseases are provided within budget heading 7083 (PP 7083) of the Ministry of Health in the approximate amount of EUR 2,000,000.00 annually, which will be allocated for this purpose in accordance with the Resolution of the Government of the Republic of Slovenia No 00725-5/2016/11 of 1 December 2016.

The NCCP 2017–2021 will serve as the framework for the planning and funding of cancer patient treatment programmes within the General Agreement for the current contractual year adopted by partners and confirmed by the Government of the Republic of Slovenia.

In order to begin implementing the new technologies, which will be published in the guidelines (including medication), uniform measures in all fields of healthcare (not only oncology) will have to be defined, taking into consideration the professionally developed and validated cost efficiency mechanisms.

Below are shown the amounts used <u>in 2017</u> to finance the measures of the National Cancer Control Programme that are already being implemented and are described in greater detail in the specific objectives.

- In the field of the primary prevention of noncommunicable (chronic) diseases and cancer, approximately EUR 2,000,000.00 will be provided from the budget in 2017 for the purpose of implementing the programmes and projects of non-profit and non-governmental organisations.

- Approximately EUR 672,700.00 will be provided in primary prevention within the implementation of prevention workshops and prevention programmes. Source: ZZZS

- The following approximate amounts will be provided for prevention programmes financed by funds from the Health Insurance Institute of Slovenia:

- SVIT programme: EUR 7,608.180.00
- ZORA programme: EUR 805,692.00
- DORA programme: EUR 6,800.011.00

- The following approximate amounts will be provided for treatment and diagnostics financed by funds from the Health Insurance Institute of Slovenia:

- Endoscopic diagnostics (thoracic diagnostics and gastroenterologic diagnostics): EUR 7,692.557.00
- Treatment surgical procedures and systemic treatment (hospital treatment includes all DRG services, in which neoplasms were recorded as the primary diagnosis (chapter II, categories C00–D48) EUR 110,035.506.00
- Treatment radiotherapy and medical oncology (specialist treatment is divided into oncology with radiotherapy (healthcare activity type 221 230) in total amount of EUR

11,684,599.46 and medical oncology (healthcare activity type 210 219) in total amount of EUR 43,920,745.45.

- Funds from the budget of the Ministry of Health will be intended for the management of the NCCP 2017–2021 in the approximate amount of EUR 80,000.00.

For next year, additional financial needs will be disclosed based on the volume of the services for the implementation of the objectives and measures according to individual fields.

## 10. Glossary of terms used:

NCCP - National Cancer Control Programme

**Incidence** and **mortality** are the absolute number of all newly discovered cases of a disease and the number of all those who have died of a disease in a specific population group in one calendar year.

**Crude incidence rate** is the number of new cases of a disease, adjusted to show their proportion within 100,000 people in the observed population; and the crude mortality rate is the number of all those who have died per 100,000 people within the observed population.

**Prevalence** is the number of all cancer patients who were alive on a selected date, regardless of when they became ill.

**Age-standardised rate** is a theoretical incidence (or mortality) rate that would be observed if the age structure of the observed population were the same as in the standard population.

**Relative survival** is an estimate of patient survival, where only a selected cancer type is taken into consideration as the cause of death. It is calculated as the ratio between the observed survival of a studied group of patients and the survival that is expected based on gender and age in a particular period in the entire population from which the patients originate.

**Oncology centre** is a name for secondary and tertiary healthcare institutions that meet the professional criteria for performing oncology treatments.

**Comprehensive rehabilitation** is a comprehensive set of measures intended to decrease the level to which the disease affects and hinders a person; i.e. it is a systematic procedure for treating rehabilitation needs, the purpose of which is to fulfil the life goals of a person affected, in agreement with this person.

**Comprehensive treatment** is an approach that, in addition to professional treatment guidelines, also takes into account the condition and the needs of individual patients.

IOL – Institute of Oncology Ljubljana

RRRS – Cancer Registry of the Republic of Slovenia

**MH** – Ministry for Health

#### SMA – Slovenian Medical Association

## **11. Appendices**

#### Appendix 1: Molecular diagnostics, objectives and measures

**Objective 1**: To establish a network of tertiary molecular diagnostics institutions and a standardised work protocol in medical genetics laboratories by the end of 2020. Responsible institution: Institute of Oncology Ljubljana in cooperation with the Ministry of Health and tertiary institutions.

- Measure 1: A network of tertiary centres that perform molecular diagnostics will be established by mid-2018. Molecular diagnostics must undergo a suitable financial evaluation beforehand and must be appropriately placed in the healthcare system. Responsible institutions: The Institute of Oncology Ljubljana, the Ministry of Health, and the management of tertiary institutions.
- Measure 2: At the same time, training for a suitable number of specialists in this field specialists in laboratory medical genetics is being planned for molecular diagnostics. In order to perform the molecular diagnostics of cancer, every laboratory must employ at least one specialist in laboratory medical genetics. Responsible institutions: The Institute of Oncology Ljubljana, the Ministry of Health, and the management of tertiary institutions.
- **Measure 3**: The tertiary institutions that will deal with the molecular diagnostics of tumours must ensure the traceability of samples and results by using a laboratory information system (LIS), and they must also provide the capacities for suitable electronic archiving of all results and their corresponding data in the field of molecular diagnostics by mid-2018. Responsible institutions: The Institute of Oncology Ljubljana and the management of tertiary institutions.
- **Measure 4**: The professional management of tertiary institutions will form a working group consisting of clinicians, pathologists, and molecular diagnostics specialists, who will, based on valid guidelines, define the types of testing for individual cancer types and carry out their financial evaluation by mid-2018. Responsible institutions: the management of the Institute of Oncology Ljubljana, the Health Insurance Institute of Slovenia.
- **Measure 5**: The institutions in the network of tertiary molecular diagnostics centres will begin using a standardised test result form for molecular diagnostics by the end of 2019, which is a part of, or an appendix to, a histopathological test result (see objective 2, measure 6 in chapter Histopathological diagnostics). Responsible institutions: heads of pathology, cytology, and molecular diagnostics departments at the Institute of Oncology Ljubljana.
- Measure 6: An insight into molecular diagnostics test results will be enabled on a trial basis for the clinics of the Institute of Oncology Ljubljana by the end of 2019. Responsible institution: the management of the Institute of Oncology Ljubljana and of the Cancer Registry.
- Measure 7: The improvement of the data included in clinical registers will be prepared by mid-2020 in the field of molecular diagnostics based on pilot testing at the Institute of Oncology Ljubljana. Responsible institution: the management of the Institute of Oncology Ljubljana and of the Cancer Registry.

**Objective 2**: Based on an analysis of evidence-based medicine and of cost efficiency, a proposal for the introduction of suitable testing will be provided by the end of 2020, whereby the introduced testing will also include the correct interpretation of the discovered DNA changes by using the databases and computer programs in the field of oncological genetics. Responsible institutions/persons: the professional heads of molecular diagnostics units in tertiary institutions.

• **Measure**: Genetic databases and computer programs that are requisite for the correct interpretation of the discovered DNA changes will be defined by the end of 2019. Licenses for genetic databases and computer programs for calculating the probability of a pathogenic impact of DNA changes will be purchased.

**Objective 3**: Based on a situation analysis and an analysis of cost efficiency, additional human resources, i.e. biostatisticians for processing molecular diagnostics sequencing data, will be provided by the end of 2019. Responsible institutions/persons: the management of tertiary institutions.

• **Measure 1**: At least one biostatistician will be employed by the end of 2018 in units dealing with the molecular diagnostics of cancer.

#### Annex 2: The objectives and measures in oncology clinical pharmacy

**Objective 1:** To standardise the preparation of antitumour medication by the end of 2021 in all hospitals that will be included in the systemic treatment of oncology patients. Antitumour medication will be prepared in a centralised unit for sterile medication preparation managed by the hospital pharmacy, and suitably educated pharmaceutical personnel that are proficient in the aseptic preparation of medication following European standards for oncology pharmacy will also work on the preparation of medication. Responsible institutions: The Ministry of Health (verification) and the Pharmaceutical Chamber of Slovenia (professional supervision and counselling).

- **Measure 1**: A situation analysis on the preparation of antitumour medication in Slovenian hospitals will be carried out in 2017.
- **Measure 2**: By the end of 2018, at least one third of Slovenian hospitals will prepare antitumour medication in a centralised unit for the sterile preparation of medication in accordance with the European standards for oncology pharmacy.
- **Measure 3**: By the end of 2020, at least two thirds of Slovenian hospitals will prepare antitumour medication in a centralised unit for the sterile preparation of medication in accordance with the European standards for oncology pharmacy.
- **Measure 4**: By the end of 2021, all Slovenian hospitals will prepare antitumour medication in a centralised unit for the sterile preparation of medication in accordance with the European standards for oncology pharmacy.

**Objective 2**: A review by a clinical pharmacist of the interactions between the systemic/support therapy for cancer treatment and the chronic therapy for treating accompanying diseases. Responsible institution: The hospital pharmacy of the Institute of

Oncology Ljubljana and the hospital pharmacy of the Golnik Clinic, the Pharmaceutical Chamber of Slovenia.

- **Measure 1**: A situation analysis of the review of the interactions between the systemic/support therapy for cancer treatment and the chronic therapy for treating accompanying diseases will be carried out in 2017.
- **Measure 2**: A pilot project for a review of the interactions will be carried out in at least one third of the Slovenian hospitals treating cancer in 2018–2019. Prior to any introduction of a new systemic treatment method, a clinical pharmacist must carry out a critical review of the interactions between the medication used (antitumour medication, support therapy, and the therapy related to accompanying diseases). The condition for this measure to be implemented is suitable information support and a sufficient number of human resources.
- Measure 3: The results of the pilot project will be evaluated in 2020.
- **Measure 4**: Based on the pilot project, recommendations for the performance of the review of interactions in all Slovenian hospitals will be given in the next National Cancer Control Programme.

**Objective 3:** To provide counselling of clinical pharmacists concerning the proper use of oral medication and to establish seamless care in the field of oncology medication (Pharmacy Practice Act; 501-01/15-14/70).

- **Measure 1**: Rules for seamless care will be drafted in 2017–2018 within the framework of the Pharmacy Practice Act. Responsible institutions: The Pharmaceutical Chamber of Slovenia and the Ministry of Health.
- **Measure 2**: A situation analysis will be carried out in 2018–2019 concerning the volume of issued oral antitumour medication and the manner of counselling when issuing oral antitumour medication in Slovenian pharmacies.
- **Measure 3**: A pilot project will be carried out by the end of 2020, in which a clinical pharmacist from the hospital where systemic treatment using oral antitumour medication is introduced issues an oral antitumour medication to every patient upon first prescription of such medication and counsels them on the proper use of such medication. The issuing is intended to provide seamless care, and counselling is mainly intended to increase the adherence to the medication consumption, focusing on the purpose of consumption (why a patient should take the medication), manner of consumption (how the patient should take the medication), and being familiar with the medication side effects and knowing what action to take if they occur (what a patient can expect). Responsible institutions: The Pharmaceutical Chamber of Slovenia and the Ministry of Health.
- **Measure 4**: Recommendations for standardised counselling upon issuing oral antitumour medication will be prepared by 2021, and seamless care in the field of oncology medication in all Slovenian hospitals will be established.