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Better noncommunicable disease outcomes: challenges and opportunities for health systems

Country assessment
BULGARIA

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Abstract

Bulgaria has one of the highest rates of premature mortality due to noncommunicable diseases (NCDs) in the European Union. The probability of dying prematurely (between the ages of 30 and 70 years) from one of the major NCDs is 24%. This report reviews the opportunities and challenges of the health system in Bulgaria for scaling up core services for the prevention, early diagnosis and management of NCDs. The report also provides examples of good practice in performance benchmarking. Policy recommendations are made for further action, based on the assessment.

Keywords
CHRONIC DISEASE – prevention and control
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Authors

Jill Farrington
Anastasia Koylyu
Laurentino Marti
Francesca Romana Pezzella
Rolando Camacho
Juan Tello
Plamen Dimitrov
Natasha Danova
Mirela Strandzheva
Galya Tsolova

Publication productions

Juan Garcia Dominguez, oversight
Christophe Lanoux, layout and typesetting
Anita Strandsbjerg and Connie Petersen, administrative oversight

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Acronyms and abbreviations

ABV	alcohol by volume
ACS	acute coronary syndrome
AMI	acute myocardial infarction
ARPharM	Association of Research-based Bulgarian Pharmaceutical Manufacturers
CPGs	clinical practice guidelines
CVD	cardiovascular disease
ESC	European Society of Cardiology
EU	European Union
EU-25	EU Member States as of 1 May 2004
EU-28	EU Member States as of 1 July 2013
GDP	gross domestic product
GP	general practitioner
HbA1c	glycated haemoglobin
HPV	human papilloma virus
MI	myocardial infarction
NCDs	noncommunicable diseases
NCPHA	National Centre of Public Health and Analysis
NGO	nongovernmental organization
NHIF	National Health Insurance Fund
PCI	percutaneous coronary intervention
PHC	primary health care
RES-Q	Registry of Stroke care Quality
RHI	Regional Health Inspectorate
RHIF	Regional Health Insurance Fund
SCORE	Systematic COronary Risk Evaluation
SDR	standardized death rate
SEEHN	South-eastern European Health Network
STEMI	ST-elevation myocardial infarction

1. Introduction and rationale

Noncommunicable diseases (NCDs) are the leading cause of death, disease and disability in the WHO European Region. The four major NCDs (cardiovascular disease (CVD), cancer, chronic obstructive pulmonary diseases and diabetes) account for the vast majority of the disease burden and of premature mortality in the Region. In Europe, NCDs (more broadly defined) accounted for nearly 89% of deaths and 85% of the disease burden in 2016, increasing the strain on health systems, economic development and the well-being of large parts of the population (*1*).

NCDs also have a significant macroeconomic impact and exacerbate poverty (*2*). Most NCDs are chronic and patients have repeated interactions with the health system and recurring and continuous medical expenses, often leading to catastrophic, impoverishing expenditure. It has been estimated that the loss of productivity due to NCDs is significant: for every 10% increase in mortality from NCDs, economic growth is reduced by 0.5%. Recent analysis by WHO suggests that every US$ 1 invested in implementing a package of 16 'best buys' (the most cost-effective NCD interventions identified by WHO) in low- and middle-income countries will yield a return of at least US$ 7 by 2030 (*3*).

This country assessment is part of a six-year programme of the WHO Regional Office for Europe on strengthening the health system response to NCDs. This multidisciplinary and interdivisional work was motivated by increasing calls by Member States for a comprehensive health system response to NCDs, at a time when pragmatic and actionable guidance on what constitutes this response was not available.

Thirteen assessments have been conducted to date in Armenia, Belarus, Croatia, Estonia, Hungary, Kazakhstan, Kyrgyzstan, North Macedonia, the Republic of Moldova, Serbia, Tajikistan, Turkey and Turkmenistan. The same approach and multidisciplinary assessment teams were used for all the country assessments, which are based on a structured guide outlined in a background paper on the role of health systems in reducing NCDs (*4*). While the same guide was used for all the country assessments, the recommendations are tailored to the context of each country. Analysis of the findings from the first 12 assessments resulted in a regional synthesis report (*5*) and a WHO high-level technical conference in Sitges, Spain, in April 2018. The outcomes of that work informed this report.

A national team was convened in December 2018 to gather materials, carry out a self-assessment in the light of the assessment guide, and draft a national perspective on the challenges and opportunities within the health system. Their findings were delivered by May 2018.

A multidisciplinary WHO expert team then visited Bulgaria during 10–13 June 2019 to validate the findings. Their programme involved meeting a wide range of stakeholders and experts involved in the prevention and control of NCDs. The methodology for this assessment is based on the original assessment guide, and the approach taken also draws on a comprehensive and aligned approach to achieving better NCD outcomes.

2. NCD outcomes

NCDs create a significant burden on a country's health system and economy, with consequences for socioeconomic development. The following section provides information on the current state and trends in NCD-related health outcomes in Bulgaria, focusing on mortality rates and outcome measures.

Life expectancy at birth in Bulgaria has increased in the last decade, reaching 74.5 years in 2015, but it remains lower than the European Union's (EU's) average rate (80.8 years) with a gap of more than seven years between men (71.1 years) and women (78.0 years) (*6*). The gap in life expectancy observed between men and women in 2017 (7.3 years) is the same as it was in 1990 (*7*).

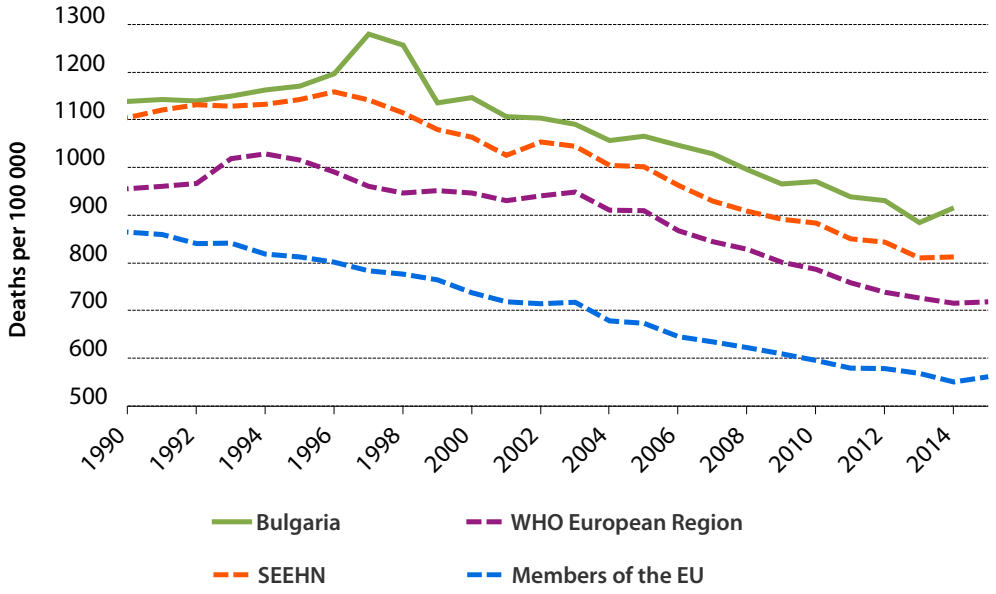
Bulgaria faces a demographic crisis characterized by a steady trend of population decline (due to low birth rates, rising mortality rates and emigration of a significant number of young people) and an ageing population. The last decade has witnessed significant changes in the population's age structure, with an insignificant increase in the share of the population up to the age of 15 years, and an increase in the share of the population aged over 65 years, a common problem among other Member States of the EU. High premature mortality rates (relative to the WHO European regional and EU averages) are likely to impact on the labour market and dependency ratio further.

One of the targets of the Sustainable Development Goals is to reduce premature mortality from NCDs by one third by 2030. The probability of premature death (from 30 to under 70 years) from four major NCDs – CVD, cancer, chronic obstructive pulmonary diseases and diabetes – in Bulgaria in 2016 was 24% for both sexes, **but the risk of NCD premature mortality was twice as high for males (32%) as for females (16%)** (*8*). In 2014 (latest figures), the standardized death rate (SDR) for the four major NCDs was 798 per 100 000 for males and 364 per 100 000 for females. These are higher than the equivalent SDRs for the WHO European Region (525 for males; 256 for females) and around twice the EU levels (360 for males; 194 for females).

Bulgaria has one of the highest SDRs for all causes (915 per 100 000 in 2014) among EU countries (EU average 550 per 100 000 in 2014) (*9*) (Fig. 1). Demographic projections demonstrate that the **total mortality rate (all ages) will remain high and unchanged at least until 2030**, given the comparatively high mortality rate among those over 65 years (*10*): according to Eurostat data (*11*), the SDR for circulatory diseases for those over 65 years was three times higher in Bulgaria than the EU-28[1] average. There are significant inequalities in SDRs across the country, between urban and rural areas and between regions: there is an almost two-fold difference by region between the highest SDR (Vidin) and lowest (Sofia city) for instance.

[1] EU-28: European Union Member States as of 1 July 2013

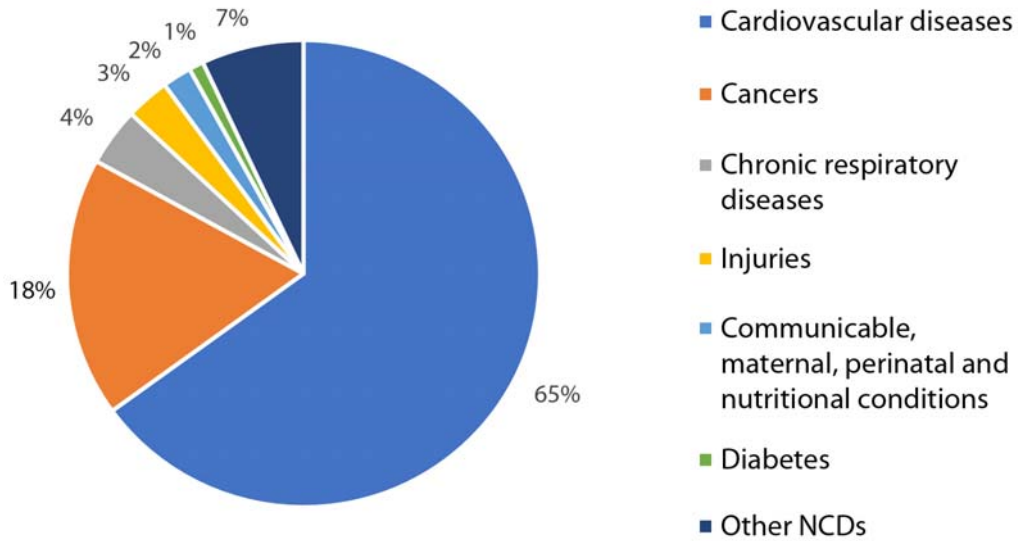
Fig. 1. SDRs, all causes, all ages in Bulgaria, the EU, South-eastern European Health Network (SEEHN) and WHO European Region



Source: European Health for All database (*9*).

Similar to other countries in the WHO European Region, **the vast majority of deaths in the country are caused by NCDs**. In 2016, about two thirds (65%) of deaths were due to CVDs followed by malignant neoplasms (cancer) (18%) and chronic respiratory diseases (4%) (Fig. 2).

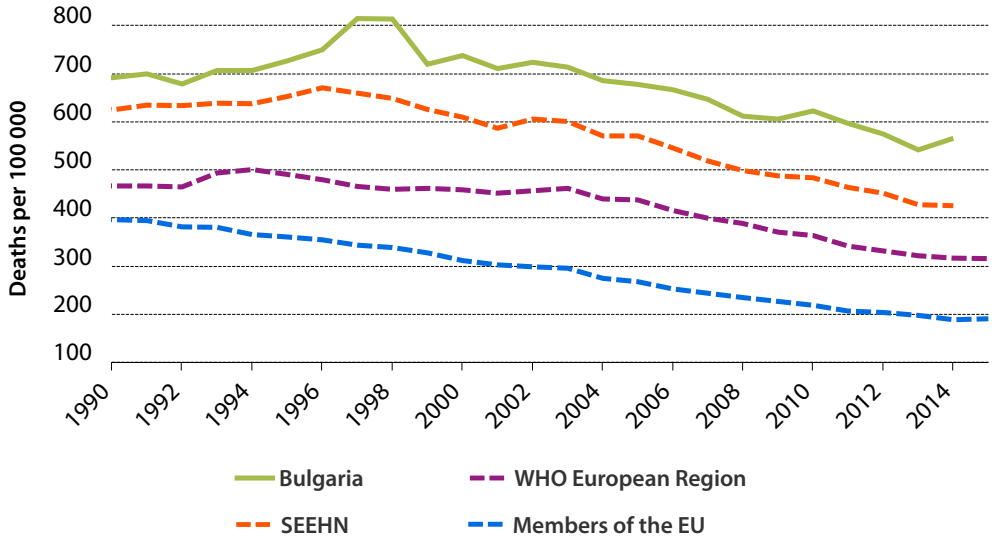
Fig. 2. Proportional mortality in Bulgaria, all causes, 2016



Source: WHO Noncommunicable Diseases (NCD) Country Profile: Bulgaria (*8*).

Over the last decade, 70 000–75 000 people have died from circulatory diseases each year. **The SDR for circulatory diseases in Bulgaria (565 per 100 000, 2014) is more than twice the EU average**, and higher than the average SDR for the SEEHN (425 per 100 000, 2014) and the WHO European Region (315 per 100 000 in 2015) (Fig. 3). The level of **premature mortality of circulatory diseases in Bulgaria is extremely high and among the highest in Europe for both sexes** (about twice the EU average in 2014). It is estimated that about 20 000 deaths or 19% of all fatalities in 2014 could have been avoided (11% for the EU).

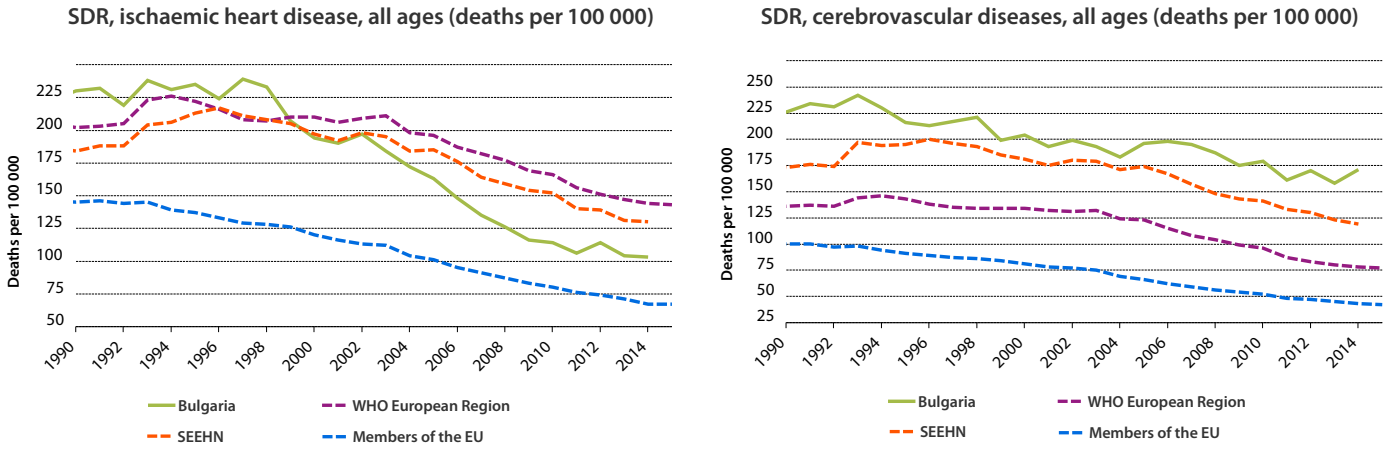
Fig. 3. SDRs for circulatory diseases, Bulgaria, the EU, SEEHN and WHO European Region



Source: European Health for All database (*12*).

Over the last two decades, the SDR for ischaemic heart disease has decreased significantly (almost halved) to 103 per 100 000 in 2014; while this is below the rates for the WHO European Region and SEEHN, it remains much higher than the EU average (67 per 100 000) (Fig. 4a). This contrasts with the trend in the SDR for cerebrovascular diseases, which has decreased slightly over the same period (to 171 per 100 000 in 2014) but is still higher in Bulgaria than in the EU, SEEHN and WHO European Region (Fig. 4b): **Bulgaria's SDR for cerebrovascular diseases is four times higher than the EU average** (171 compared with 43 per 100 000 in 2014) and more than seven times higher than countries with the lowest SDR such as France (22 per 100 000). This difference may reflect the policies for investment in advanced technology and efficient care for acute coronary syndrome (ACS) compared with stroke.

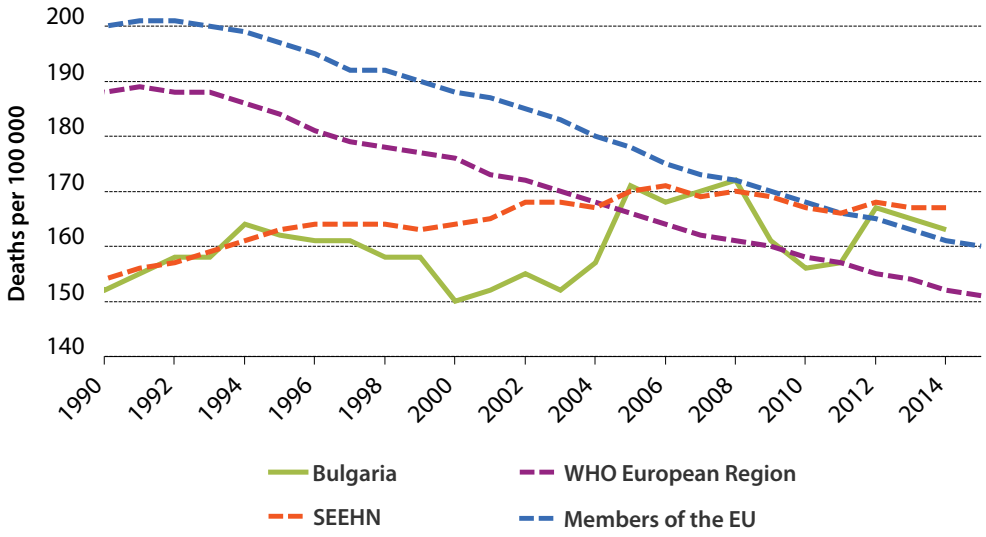
Fig. 4. SDRs for (a) ischaemic disease and (b) cerebrovascular diseases, Bulgaria, the EU, SEEHN and WHO European Region



Sources: European Health for All database (*13, 14*).

Malignant neoplasms (cancer) rank second in the structure of mortality. The upward trend in Bulgaria is apparent for both sexes and contrasts with the overall declines in SDRs seen in the WHO European Region and EU (Fig. 5). Bulgaria had 35 378 new cases of cancer and 19 139 cancer deaths in 2018. **Bulgarians have a 1 in 4 (25.1%) risk of developing cancer before the age of 75 years** (30.1% for men, 21.2% for women). The most frequent cancers (excluding skin cancer) are colorectal, prostate, lung, breast and bladder (*15*). Lung cancer is the leading cause of cancer mortality. The SDR for colorectal cancer is close to the EU level, but cervical cancer (4.7 per 100 000) is more than two times higher (2.1 per 100 000).

Fig. 5. SDRs for malignant neoplasms, Bulgaria, the EU, SEEHN and WHO European Region



Source: European Health for All database (*16*).

Five NCDs feature among the top 10 causes of death and disability as measured by the age-standardized disability-adjusted life years rate (per 100 000 population): ischaemic heart disease (3718.6), stroke (2472.0), lung cancer (718.0), diabetes (649.5) and chronic obstructive pulmonary disease (636.8) (*7*). **The combined risk factors that drive the most death and disability are high blood pressure, dietary risks and tobacco.**

According to the European Health Interview Survey (*17*), 3 out of 10 people in Bulgaria live with hypertension, 3 out of 100 with asthma, and 3 out of 100 with chronic depression. The prevalence of these and other chronic diseases vary widely depending on education. Those with the lowest level of education are almost two times more likely to live with diabetes or asthma than those with the highest level of education. To a large extent, this may be due to the higher proportion of older people who have attained a lower level of education. Depending on income, large differences in the self-assessment of health status are observed.

3. Coverage of core NCD interventions and services

According to WHO, up to 80% of heart disease, stroke and type 2 diabetes and over a third of cancers could be prevented by eliminating shared risk factors, mainly tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol (*1*).

This section explores coverage of core population interventions to control behavioural risk factors (tobacco, alcohol, unhealthy diet and physical inactivity) and individual services (CVD, diabetes and cancer) that are closely linked with improving NCD outcomes. Core services are evidence-based, high impact, cost-effective, affordable and feasible to implement in a variety of health systems. The core services reviewed in the country assessments are closely linked to

Table 1. Core population and individual services for NCDs

Population interventions	Individual services
Wide range of anti-smoking interventions • Raise tobacco taxes to reduce affordability • Smoke-free environments • Warnings of dangers of tobacco and smoke • Bans on advertising, promotion and sponsorship • Quit lines and nicotine replacement therapy	**CVD and diabetes – first line** • Risk stratification in PHC, including hypertension, cholesterol, diabetes and other CVD risk factors • Effective detection and management of hypertension, cholesterol and dabetes through multidrug therapy based on risk stratification • Effective primary prevention in high-risk groups and secondary prevention after acute myocardial infarction (AMI) and stroke including acetylsalicylic acid **CVD and diabetes – second line** • Range of rapid response and secondary care interventions after AMI and stroke*
Interventions to prevent harmful alcohol use • Pricing policies on alcohol including taxes • Restrictions or bans on advertising and promotion • Restrictions on the availability of alcohol in the retail sector • Minimum purchase age regulation and enforcement • Allowed blood alcohol level for driving*	**Diabetes** • Effective detection and general follow-up • Patient education and intensive glucose management • Hypertension management among diabetes patients • Prevention of complications (for example, eye and foot examinations) • Patient education on healthy eating and physical activity
Interventions to improve diet and physical activity • Reduce salt intake and salt content in foods • Replace *trans*-fats with unsaturated fat • Implement public awareness programmes on diet and physical activity • Reduce free sugar intake* • Increase intake of fruit and vegetables • Reduce marketing pressure of food and non-alcoholic beverages to children* • Promote awareness about diet and physical activity	**Cancer – first line** • Prevention of liver cancer by vaccination against hepatitis B • Vaccination against human papilloma virus (HPV) as appropriate if cost-effective according to national policies • Screening for cervical cancer and treatment of precancerous lesions **Cancer – second line** • Early case-finding for breast cancer and timely treatment of all stages • Population-based colorectal cancer screening at age > 50 linked with timely treatment

* Indicates interventions are services added to the list of the Global action plan for the prevention and control of NCDs 2013–2020 to allow a more comprehensive assessment (*1*).

the Global action plan for the prevention and control of NCDs 2013–2020 (*1*) and the Action Plan for the Prevention and Control of NCDs in the WHO European Region 2016–2025 (*18*). A standard set of core interventions and services are used for all country assessments and are summarized in Table 1. The assessment teams evaluated each service on a three-point scale (limited, moderate and extensive). The criteria for scoring were developed by WHO and can be found in the assessment guide (*4*) and in Annexes 1–3 of this report.

3.1 Population interventions

This section assesses the coverage of core population interventions and services for improving NCD outcomes.

3.1.1 Tobacco

Table 2 shows the assessment of implementation of population-based interventions for tobacco control.

Table 2. Score card for core population-based interventions for tobacco control

Intervention	Rating	Criterion for rating
Raise tobacco taxes	**Extensive**	In Bulgaria, a pack of cigarettes costs around 5 Bulgarian leva (US$ 2.9), of which more than 80% is (value-added and excise) tax. The affordability of cigarettes has not changed since 2008.
Smoke-free environments	**Limited**	Enclosed public places, as well as some open public places (especially for children) are smoke-free but not fully enforced (enforced in schools, but still a current practice in hospitals, restaurants and public working places). Bans on smoking in public places do not cover shisha and novel tobacco products; these products can be used in restaurants and bars.
Warnings of dangers of tobacco and smoke	**Extensive**	Requirements for packaging follow the EU Tobacco Products Directive: warning labels and graphics cover 65% of the package front and back and include a quit-line number (#070010323).
Bans on advertising, promotion and sponsorship	**Limited**	Bans exist on some direct and indirect advertising and promotion of tobacco products. Direct advertisement of heated tobacco products is allowed.
Quit lines and nicotine replacement therapy	**Moderate**	Bulgaria only provides cessation support in 28 special facilities in the Regional Health Inspectorates (one per region), but lacks evidence on quit rates. Nicotine replacement therapy can be purchased over the counter in a pharmacy but is not cost-covered; a toll-free quit line is available 24 hours a day with an automatic message service to make appointments.

The prevalence of current tobacco smoking among adults (aged 15+ years) in Bulgaria in 2017 was 36.0% according to the latest national surveys, with higher rates for men (45.0%) than women (28.0%); WHO estimates are slightly higher at 39.5% for both sexes, and 43.5% for men and 35.4% for women (*19*). According to National Statistics Institute data, the average number of cigarettes per person per household – and expenditure on cigarettes – has increased over the period 2010–2017. Prevalence of current tobacco smoking among adolescents aged 13–15 years was 27.4% in 2015, higher for girls than boys, according to the Global Youth Tobacco Survey 2015 (*20*). At the same time according to a 2013/2014 survey (*21*), Bulgarian adolescents rank among the highest in terms of weekly use of cigarettes in the cross-national comparison. Girls smoke more often than boys: 30% of 15-year-old girls smoke at least once a week versus 21% of boys at that age (which puts Bulgaria in second place after Greenland).

In 2005, Bulgaria ratified the WHO Framework Convention on Tobacco Control, but not the Protocol to Eliminate Illicit Trade in Tobacco Products. Nationally, tobacco control is regulated by various legislation (*22*) including the acts amending and supplementing the Law on Health (2008, 2009, 2010) – known as the Health Act – and the Law on Tobacco and Tobacco Products (2016), which transposes the Tobacco Products Directive (2014/40/EU) into national law. Individual and population strategies are embedded within the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020.

Taxation

According to the Excise Duties and Tax Warehouses Act, the specific excise duty for tobacco is 101 Bulgarian leva per 1000 pieces, and the proportional excise duty is 28% of the sale price; however, the total excise duty should not be less than 177 leva per 1000 pieces. Thus, if the price of the cigarette pack is 5 leva (the average price of the most frequently sold cigarettes), then the specific excise duty is 2.02 leva, and the proportional excise duty is 1.4 leva (28% of 5 leva). Adding these two figures gives a total excise duty of 3.42 leva or 68.4% of the sale price. Value-added tax is 20%; hence, the total tax exceeds 80%. However, the affordability of cigarettes has not changed since 2008 (*19*).

According to the Health Act, 1% of the revenues to the state budget from excise taxes on tobacco products and spirits should be used to finance national programmes to restrict smoking and the abuse of alcohol, and to prevent the use of narcotic drugs.

Smoke-free environments

According to the Health Act, smoking is prohibited in indoor public places, as well as in the following open public places: the sites and pavements adjacent to nursery schools, kindergartens, schools, pupils' dormitories and places where social services are provided to children, playgrounds, places where events for children and pupils are organized, sports facilities, summer cinemas and theatres, and sports and cultural events. However, enforcement is limited. Smoking violations consist of fines on the patron, as well as the smoker, but not on the establishment. A system for control, including citizen complaints and further investigations, is in place, but not enforced: the Regional Health Inspectorates (RHIs) perform between 180 000 and 200 000 inspections per year uncovering 500–1000 violations, but the administrative procedure seems to be inefficient and inspectors are not empowered. The definition of "indoor place" has been challenged by restaurateurs, among others, but is now being addressed by the additional provisions. Additionally, in glass-walled restaurants the use of all types of tobacco products is permitted. Moreover, bans on smoking in public places do not cover shisha and novel tobacco products.[2] These products can be used in public places.

Warnings

Bulgaria follows the packaging requirements of the EU Tobacco Products Directive. Health warnings are legally mandated to cover 65% of the front and back of the cigarette package. They appear on each package and any outside packaging and labelling used in the retail sale, and they describe the harmful effects of tobacco use on health. Moreover, health warnings rotate on packages, are written in the principal language of the country and include a photograph or graphics. The law also mandates font style, font size and colour for package warnings. A quit-line number (#070010323) is displayed on the package. There is no plain packaging (*19*).

The Child Protection Act states that the supply and sale of tobacco products to children are prohibited.

[2] According to the decision of the Conference of the Parties to the WHO Framework Convention on Tobacco Control FCTC/COP8(22) of 6 October 2018, heated tobacco products are recognized to be tobacco products and are therefore subject to the provisions of the WHO Framework Convention on Tobacco Control (*23*).

Bans

There are bans on some direct and indirect advertising and promotion of tobacco products: on television and radio, in local magazines and newspapers, and on the Internet. Cigarettes are often displayed and there are no warnings at points of sale. Advertising on billboards is still in place. Besides, promotion campaigns (e.g., in shopping malls) and advertising of novel and emerging products (such as heated tobacco products) are common. There is no explicit ban on sponsorship (*19*).

Smoking cessation services

Bulgaria provides cessation support in special facilities located in each of the 28 RHIs, with opening hours from 9:00 to 17:00. Data on quit rates are not available. Nicotine replacement therapy can be purchased over the counter in a pharmacy but is not cost-covered. The toll-free quit line is available 24 hours a day with an automatic message service to make appointments. Clinical practice guidelines (CPGs) for smoking cessation have been developed (2013), but no evidence on implementation is available. General practitioners (GPs) assess smoking by using a risk factors template, but specific training for GPs or nurses to provide counselling is not available. The NCPHA provides information material to guide health professionals.

3.1.2 Alcohol

Table 3 shows the assessment of implementation of population-based interventions for alcohol control.

Table 3. Score card for core population-based interventions for alcohol control

Intervention	Rating	Criterion for rating
Raise taxes on alcohol	**Limited–Moderate**	An excise tax exists on beer and spirits. The tax follows the price index and is related to alcohol content. There is a special tax on beer but not on products attractive to young people.
Restrictions, bans on advertising and promotion	**Limited**	Regulatory frameworks exist to regulate content and volume of alcohol marketing including direct and indirect marketing. Direct advertising of spirits is prohibited. There is no explicit ban on sponsorship.
Restrictions on availability of alcohol in retail sector	**Limited–Moderate**	Regulatory frameworks exist on serving alcohol in government and some educational institutions. There are restrictions for on-/off-premise sales of alcoholic beverages for specific days, places, events and to intoxicated persons.
Minimum purchase age regulation and enforcement	**Limited–Moderate**	The national legal minimum age for on-/off-premise sales of alcoholic beverages is 18 years, but enforcement is weak (for example sellers do not always request proof of age identification).
Allowed blood alcohol level for driving	**Limited**	The maximum blood alcohol content is 0.5 g/L for novice and professional drivers.

In 2016, the average total alcohol consumption (recorded and unrecorded) per person (aged 15+ years) in Bulgaria was estimated to be 12.7 L of pure alcohol, which is higher than the WHO European Region average of 9.8 L (*24*). Additionally, a large difference between sexes was observed: men consumed 21.0 L/year and women 4.9 L/year. The proportion of lifetime abstainers was 13.9%. Recorded alcohol consumption showed that spirits (43%) are more popular than beer (39%) and wine (17%).

[3] Defined as consumption of at least 60 g or more of pure alcohol on at least one occasion in the past 30 days

WHO estimates that alcohol consumption has increased since 2010 (baseline: 12.0 L per person) (*24*). This trend is confirmed by national data: according to National Statistical Institute data for the period 2001–2017, Bulgaria has witnessed a significant increase (by 10.7 L) of alcohol consumption on average per person, as well as a significant increase in alcohol expenses per household (*25*). Between 2010 and 2016, the alcohol-attributable mortality rate increased in Bulgaria (*26*).

One in three (33.4%) of the general population (aged 15+ years) reported heavy episodic drinking,[3] with rates three times higher among males (52.1%) than females (16.1%). Levels are even higher among regular drinkers (50.6%), particularly male drinkers (65.9%).

According to a 2013/2014 survey of students from grades 5, 7 and 9 (*21*), Bulgarian adolescents rank among the first in terms of weekly use of alcohol in the cross-national comparison (43 countries). About 24.6% of young people aged 11–15 years (31.7% of boys and 17.5% of girls) were consuming alcohol weekly in 2014 (*27*).

Nationally, alcohol consumption is regulated by the Health Act. There is a provision on alcohol control in the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020.

Guidelines on good practices to limit alcohol abuse were developed in 2018 for medical professionals by the NCPHA to guide specialists of RHIs.

Taxation

There is an excise tax on beer and spirits, but not for wine (*24*). The tax follows the price index and varies according to the alcohol content. Regulated alcohol and alcoholic beverages that have an excise tax include:

- beer or mixtures of beer with over 0.5% alcohol by volume (ABV);
- still wines with over 1.2–15% ABV;
- still wines with 15–18% ABV, when the alcohol is produced by fermentation;
- sparkling wines (champagne) with 1.2–15% ABV when the alcohol is produced by fermentation;
- other fermented beverages with 1.2–10% ABV, or with 10–15% ABV when the alcohol is produced by fermentation;
- intermediate products with an ABV level between 1.2% and 22% that are not listed above; and
- ethyl alcohol, in most cases with a high alcohol content exceeding 22% ABV.

Warnings

There are no requirements for packaging or labelling, or for health warnings to be placed on consumer packaging.

Bans

According to the Health Act, the direct advertising of spirits is prohibited. The indirect advertising of spirits and the advertising of wine and beer should not: be targeted to persons below the age of 18 and broadcast on television programmes or published in the press for youngsters; use persons below the age of 18; relate the use of alcoholic beverages to sports and physical achievements or driving; and contain untrue assertions as to the health benefits and social or sexual well-being or present abstinence or moderation in a negative light. Additionally, the indirect advertising of spirits may not be broadcast on radio and television before 22:00.

Availability

According to the Health Act, the sale of alcoholic beverages is prohibited to persons under 18 years old; within the vicinity of kindergartens, schools, dormitories and medical establishments; and at sports events and public events organized for children and pupils. Sale is also prohibited to intoxicated persons (Health Act).

Some municipalities issue ordinances to address the use of alcoholic beverages and drugs on streets, public squares and parks, public green spaces and other public places. These ordinances include specific points on the access of persons who have consumed alcohol and other drugs in buildings and places intended for public use such as office buildings (open to the public) (*24*).

There are also restrictions for on-/off-premise sales of alcoholic beverages for specific days (*24*).

Purchase age

According to the Health Act and the Child Protection Act, the sale of alcoholic beverages is prohibited to persons below the age of 18 years; however, identification are not always required to buy alcohol. Fines for violation are in place and RHIs do inspections but related data is not fully or systematically exploited.

Blood alcohol level for driving

The national maximum legal blood alcohol concentration when driving a vehicle has been set at 0.5 g/L for general, novice and professional drivers (*24*).

3.1.3 Nutrition and physical activity

Table 4 shows the assessment of implementation of population-based interventions for nutrition and physical activity.

National studies on dietary intake and nutritional status are occasionally conducted. In the context of the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020, a survey was conducted to gather reliable data on the prevalence of major risk factors. Individual standardized interview questionnaires were administered to gather data initially in 2007, and successively in other studies of dietary and nutritional status. Children and students of all age groups from nurseries, kindergartens and schools were randomly assigned based on the registries of the Ministry of Education and Science for the academic year 2013/2014 (*29*). The annual household budget survey in Bulgaria, relying on a representative sample of families, conducted by the National Statistical Institute, is used to monitor and outline the trends in food and drink consumption. The system is based on assessing the food basket through food items bought from the market (*30*). The national food composition database is constantly updated and used for assessment of energy and nutrients intake. The database contains information on nutrients in raw products and prepared national dishes. It is used by RHIs for monitoring food in child settings. Bulgaria is also participating in WHO-specific surveys, notably the first five rounds of the WHO European Childhood Obesity Surveillance Initiative.

A high proportion of people in all age groups have an average daily **intake of sodium** above the upper limit of safe intake, mainly from bread, cheese and meat products due to salt added during food processing and food production (*29*). Data from 2004 show that salt intake in Bulgaria was 12.5–14.5 g/day for men and 11.4–16.6 g/day for women (*31*). A national survey in 2016, using only spot urine samples, revealed that the average concentration of salt in the urine was 7–9 g/day. However, a survey done in 2000 in Varna (*32,33*) that used 24-hour urinary sodium excretion showed that the average concentration of salt in the urine of

participants was 14 g/day, which is higher than the WHO recommendation of less than 5 g/day. Approaches towards salt reduction include monitoring, industry involvement and food reformulation, labelling and awareness initiatives (*31*,*32*). For example, since 2016 the country has been following the EU regulation (No 1169/2011) on the provision of food information to consumers (*34*), and all labels include the obligatory nutrition declaration. However, the trend of high daily intake of salt (over 5 g) among the population continues – 51.3–87.9% for individuals over 20 years (*33*).

Table 4. Score card for core population-based interventions for nutrition and physical activity

Intervention	Rating	Criterion for rating
Reduce salt intake and salt content in foods	**Limited**	Consumption of salt is very high with no evidence of reduction. One of the expected results of the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 is to achieve a long-term goal of reducing salt consumption to less than 5 g per person per day. Approaches include monitoring, industry involvement and food reformulation, labelling and awareness initiatives. Legal regulation for healthy nutrition of schoolchildren includes cooking recommendations and restrictions on the products served and sold in schools settings.
Virtually eliminate *trans*-fatty acids from the diet	**Moderate**	No evidence is available on the reduction of *trans*-fats from the diet. One of the expected results of the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 is reducing the use of industrially produced trans-fatty acids (hydrogenated plant oils) in food provision. Relevant EU regulations were adopted in 2019. Initiatives on food reformulation and labelling exist. Legal regulation for healthy nutrition of schoolchildren includes cooking recommendations and restrictions on the products served and sold in school settings.
Reduce free sugar intake	**Limited**	Sugar consumption is high with no evidence of reduction. Legal regulation for healthy nutrition of schoolchildren includes cooking recommendations and restrictions on the products served and sold in school settings.
Increase intake of fruit and vegetables	**Moderate**	According to national data from 2011, the average household consumption of fruit and vegetables was only 323 g per person per day. Legal regulation for healthy nutrition of schoolchildren includes providing fruits and vegetables in schools. A national ordinance recommends high daily intake of fruits and vegetables.
Reduce marketing pressure of food and non-alcoholic beverages to children	**Moderate**	WHO marketing recommendations have been acknowledged. A framework for responsible commercial communication on food and drinks was adopted in 2010. Despite globally agreed rules on the promotion, production and marketing of foods for infants and children and nearly 40 years since the introduction of the International code of marketing of breast-milk substitutes, a WHO study finds many companies in Bulgaria are not compliant with the rules (*28*). Legal regulation for healthy nutrition of schoolchildren includes restrictions on the products sold in school settings.
Promote awareness about diet and activity	**Moderate**	Within the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020, measures have been taken to improve nutrition and increase physical activity. Dietary guidelines for various population groups have been developed. Educational materials exist and are being distributed in PHC. However, no professionals are dedicated to counselling, and no evidence is available on enforcement. National awareness-raising campaigns are organized. School curriculum should include training on healthy lifestyles.

Levels of trans-fats are not monitored nationally, while **fats intake** is monitored using national food composition data and in surveys. According to 2007 estimates, the adult population consumed 8.1% of their total calorie intake from saturated fatty acids (*31*). According to national data, consumption of margarine gradually declined in the period 2010–2017 (*30*). A new EU regulation (*35*), adopted in 2019 and affecting food placed on the market on 2 April 2021, sets a maximum of 2 g per 100 g of trans-fats, other than naturally occurring in fat of animal origin, in food intended for the final consumer and food intended for supply to retail. The Bulgarian national nutrition council has initiated work accordingly.

According to national data, in 2014 the consumption of **sugar and sugar products** among people aged over 19 years was in the range of 19.1–33.0 g/day (*29*). About 26% of children consume savoury snacks and 18% of children drink soft drinks containing sugar more than three days per week (*36*). According to a WHO study of the commercial baby food market (*28*), in around half or more of products, more than 30% of energy was provided by sugars and more than 4 in 10 products had 40% or more of energy from sugars. According to a 2013/2014 survey (*21*), sweet foods (43.8%) and non-alcoholic beverages containing sugar (34.5%) are among the foods most commonly consumed daily by adolescents. Bulgarian adolescents are ranked among the first in the cross-national comparison of consumption of sweet foods and non-alcoholic beverages containing sugar. At the same time a national study in 2014 observed a favourable tendency for reduced consumption of soft drinks containing sugar (*29*).

WHO recommends that individuals consume a minimum of 400 g of **fruit and vegetables** per day. According to national data from 2014, the average daily consumption of (mainly fresh) fruit and vegetables was 402.1 g/day (*29*). A national study in 2014 observed that the average daily consumption of fruits and vegetables has increased in almost all age groups, compared with data from 1998 (*29*). However, according to the annual household budget survey in 2017, the average daily consumption of fresh and frozen fruits and vegetables per person was 271 g (*31*). Only 35% of children consume fruits every day and 27% eat vegetables (*36*). Ordinance No. 37 for healthy nutrition of schoolchildren recommends 520–650 g/day of fruits and vegetables for schoolchildren aged 6–19 years.

The prevalence of **overweight and obesity**, defined as a body mass index greater or equal to 25 kg/m^2 or 30 kg/m^2 respectively, among adults was 61.7% (*37*) and 25% (*38*) respectively in 2016. The prevalence of overweight was higher among men (68.9%) than women (54.4%) but not significantly different for obesity. During 2015–2017, 30% of seven-year-old boys and 29% of seven-year-old girls were overweight, while 16% and 11% of the same-aged boys and girls respectively were obese (*36*).

WHO recommends at least 150 minutes of moderate-intensity **physical activity** per week combined with muscle strengthening exercise. Only 26% of adults over 20 years old (32% of men and 21% of women) and 33% of children (42% of boys and 24% of girls) are sufficiently physically active (*39*). Overall, daily physical activity decreases with age for both boys and girls; the greatest decline occurs in girls aged 11–13 years and boys aged 13–15 years (*21*).

The National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 contains provisions on nutrition and physical activity. Other provisions are in Ordinance No. 37 on the healthy nutrition of schoolchildren (2009), Ordinance No. 6 on healthy nutrition of children aged 3–7 years in school and child care settings (2011) and Ordinance No. 2 on the healthy nutrition of children aged 0–3 years in child care settings (2013). Nutrition guidelines for different age groups – for adults (2006), children aged 3–6 years (2014) and schoolchildren aged 7–19 years (2008) – are also available.

The National Strategy for Physical Education and Sports Development 2012–2022 was adopted in 2011. National recommendations on physical activity for health are currently being developed. According to the Health Act, the curriculum of kindergartens and schools provide pupils with training in healthy nutrition, healthy environment, healthy lifestyles, health risks related to smoking, use of alcohol and narcotic drugs, sexual behaviour, prevention of sexually transmitted diseases and prevention of undesired pregnancy. In primary and secondary schools, 3–3.5 hours of physical education per week are mandatory (*39*).

Information campaigns are organized. For example, Move means health – World day of physical activity is a national campaign established in 2002, run by the Ministry of Health and funded from regional and municipality budgets (*39*).

A framework for responsible commercial communication on food and drinks was adopted by the National Council for Self-Regulation in 2010 (*31*). There are initiatives to introduce labelling of food. Together with producers' associations, national standards have been developed for meat-based products, cheeses and bread. A national logo indicates low levels of salt, fat and other additives. Bread containing low levels of salt exists (1.2 g/100 g). The EU Pledge (*40*) is also used as a reference to accelerate the process, but resistance from food producers is observed.

Counselling on nutrition and physical activity is offered as part of reimbursed PHC services by GPs and specialists (*39*).

3.2 Individual services

This section assesses individual services for delivering core NCD interventions and for achieving the relevant voluntary global NCD targets (*41*), in particular that at least 50% of eligible people receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes, and that a 25% relative reduction in the prevalence of raised blood pressure is achieved or the prevalence of raised blood glucose is contained. These aims would be supported by action to achieve an additional global NCD target, such as 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities. The core interventions are selected from the list of very or moderately cost-effective interventions identified by WHO in the Global action plan for the prevention and control of NCDs (*1*) and updated at the Seventieth World Health Assembly in May 2017 (*42*).

These services include early detection, proactive disease management and secondary prevention for CVD and diabetes and selected interventions for cancer. Effective delivery of most of these services requires people-centred PHC with well-organized links to population outreach activities in acute and chronic care settings. Clinical guidelines for CVD, cancer, chronic respiratory diseases and diabetes were reported as being utilized in at least 50% of health facilities in 2017, and the proportion of PHC centres reported as offering CVD risk stratification was estimated at more than 50% in 2017 (*8*). Preliminary results for 2019 are unchanged.

The prevalence of behavioural risk factors for NCDs is reported in section 3.1. The prevalence of other risk factors is reported below.

3.2.1 CVD

Table 5 shows the assessment of implementation of individual services for CVD.

Risk stratification in primary care

There is a national programme of annual health checks for insured adults over 18 years. The check is carried out by the GP, who is obliged to provide insured individuals with information on the type and frequency of medical check-ups and examinations, displayed clearly within the medical facility. The annual health check includes: complete medical history and objective health status, laboratory blood and urine tests, completion of a questionnaire, risk group stratification, etc. Tests to measure cholesterol, triglycerides and blood glucose and an electrocardiogram may be performed within the same calendar year but not as part of – or repeated at – the annual health check. During a check-up, and based on the patient's age, the

GP orders a test for cholesterol levels – triglycerides and high-density lipoprotein – in order to determine CVD risk. Risk is calculated using the ESC SCORE[4] risk prediction charts, which estimate the 10-year risk of fatal CVD by gender, age, systolic blood pressure, total cholesterol and smoking status (*43*). Tests are performed in certified medical-diagnostic laboratories contracted with the National Health Insurance Fund (NHIF).

Even though mandatory, the frequency of preventive check-ups among the insured is quite low: just 38% of the population in 2018 according to NHIF data. There are penalties for non-participation in the health checks programme. Individuals who skip the annual medical check-up lose their health insurance for one month in the following year and can also be fined by the RHIs.

Following the health check, GPs stratify people according to risk, recording it in the risk assessment card for disease development. In 2017, 91% of all people who had undergone an annual check-up had such a card (overall 2 115 596 cards). Based on these cards and according to SCORE, GPs found that 570 350 people aged over 18 years are at risk, 16 327 people at high-risk and 1661 people at very high-risk of developing CVD.

Table 5. Score card for individual services for CVD prevention and management

Intervention	Rating	Criterion for rating
Risk stratification in primary care	**Moderate–Extensive**	Annual health checks are provided for insured adults over 18 years with a penalty for non-participation. Coverage of the eligible population is relatively low. Calculation of 10-year CVD risk uses the ESC SCORE charts. CVD risk is documented for 91% of those checked and GPs record ambulatory check-ups.
Effective detection and management of hypertension	**Moderate**	Blood pressure is measured during routine health checks in PHC or opportunistically. WHO estimates that 28.4% of adults had raised blood pressure in 2015 (27.7% according to a 2014 national survey). Proportions that are detected in PHC (observed/expected) seem variable. Antihypertensive medication is prescribed (branded not generic) and co-payment is required. Non-drug treatment through lifestyle counselling is non-systematic and relatively underdeveloped. Systematic efforts to increase adherence are not evident. Use of hypertension registers is not systematic.
Effective primary prevention in high-risk groups	**Moderate**	High-risk patients can be identified, for example, through risk stratification following routine health checks or by generating a list of patients with existing CVD (not routinely done). Acetylsalicylic acid is included in the treatment regimen. Effectiveness of primary prevention is not monitored. Active management to reduce CV risk or achieve treatment targets is not evident in PHC.
Effective secondary prevention after AMI	**Moderate**	A multidrug regimen exists, apparently following European guidelines. Drugs are not free after hospitalization; the usual co-payment exists. Standard follow-up offered by cardiology consists of two appointments within three months. No systematic overview of adherence is seen, and the proportion of post-MI patients taking medication as prescribed by the follow-up seems variable (20–90%).
Rapid response and secondary care after AMI and stroke	**Limited**	There is no overview or monitoring of the proportion of people with AMI or stroke who had received medical assistance within six hours of first symptoms. Time of admission/discharge to hospital is recorded but time to intervention is not routinely noted. A national register of ACS/stroke does not exist; no national, regional or hospital overview of quality indicators is maintained. Around 29 centres independently enter data into an international stroke registry (Registry of Stroke care Quality (RES-Q)) and were achieving a door-to-needle time of around 55 minutes by 2019.

[4] ESC: European Society of Cardiology; SCORE: Systematic COronary Risk Evaluation

Effective detection and management of hypertension

WHO estimates that 28.4% of adults (age-standardized rates; both sexes) had raised blood pressure in 2015 (*44*), and rates were higher for men (33.6%) than women (23.0%). The WHO estimates are similar to the findings of the national NCD risk factor survey in 2014 (27.7% both sexes).

Blood pressure is measured during routine health checks in PHC or opportunistically when the patient visits for other reasons. In two of the practices visited, the number of registered hypertensive patients was compared to the estimated prevalence (28% according to the WHO estimate of raised blood pressure). The observed number of patients registered with hypertension was close to those expected in one practice and lower in the other one.

GPs can diagnose hypertension without confirmation by a specialist. Patients diagnosed with hypertension may be seen free-of-charge by the GP four times a year or two times a year by a specialist (i.e. cardiologist); further access is charged to patients. Antihypertensive medication is prescribed (branded not generic) and partial reimbursement may be available (see *Challenge 11*). According to the National Framework Agreement on medical activities, negotiated between the Bulgarian Medical Association and the NHIF, patients diagnosed with hypertension (ICD-10 codes I10 and I11)[5] can receive only one prescription for one health condition per month including no more than three medicines (reimbursed 100%). Non-drug treatment through lifestyle counselling is non-systematic and relatively underdeveloped. Hypertension health schools do not exist nor does systematic therapeutic patient education. The GP is responsible for providing lifestyle counselling. Systematic efforts to increase adherence are not evident.

The Bulgarian Society of Cardiology is a member of the ESC and has endorsed the ESC and the European Society of Hypertension guidelines for the management of arterial hypertension (*45*).

Effective primary prevention in high-risk groups

High-risk patients can be identified, for example, through risk stratification following health checks or by generating a list of patients with existing CVD (not routinely done) using practice software. Acetylsalicylic acid is included in the treatment regimen for those at high risk. The effectiveness of primary prevention in high-risk groups is not known or monitored. Active management to reduce CV risk or achieve treatment targets was not evident in the PHC centres visited.

The number of examinations and the number of visits for dispensary observation for chronically ill people depend on their health status and their diagnosis. The dispensary observation of an insured person is carried out on the basis of a one-time "referral for Consultation or Concurrent Treatment" (Ministry of Health–NHIF No. 3) by the GP (see *Challenge 6*). If the health specialist in charge of the dispensary observation process changes, the GP issues a new referral. In this process, certain referrals include tests such as echocardiography and Doppler ultrasound, in addition to examination by the medical specialist. Where necessary, other specialized activities and examinations are also carried out.

In 2017, the highest numbers of dispensary observations by a GP for insured individuals were recorded for diseases of the circulatory system – 1 576 706 people – and diseases of the endocrine system and nutritional and metabolic diseases – 397 932 people. The number of examinations in dispensary observation performed by GPs for an insured individual in a Regional Health Insurance Fund (RHIF) does not deviate significantly from the country's average and is within the limits agreed in normative regulations. In 2017, the average number of primary medical dispensary check-ups was 61 per 10 000 insured individuals (compared with 69 in 2016).

[5] ICD-10: International Classification of Diseases, tenth edition

In 2017, the rate of people who visited a medical specialist for dispensary check-up was 1.29 per dispensarized insured individual (compared with 1.26 in 2016).

Effective secondary prevention after AMI or stroke

There are no national CPGs for ACS, but **multidrug regimen treatment is offered for secondary prevention**, following European guidelines. Drugs are not free after hospitalization, but partial reimbursement may be available (see *Challenge 11*). The standard follow-up after AMI that is offered by cardiology is for two appointments: one within a month, the second within three months. The patient can then have an annual check-up by a cardiologist. Only a cardiologist can change the medication; the GP continues to prescribe the same medicine (repeat prescription).

No systematic overview of adherence is seen but the proportion of post-MI patients taking medication as prescribed by the follow-up seems variable. It would be interesting to see the one-year readmission rates for these patients. There is no ACS registry to monitor quality of care during hospitalization and after AMI. In principle, information could be obtained by the NHIF or from a limited number of published studies. For example, according to a 2009 study (*46*) at discharge aspirin, beta-blockers, angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers and statins were used in 85%, 79%, 66% and 43% of cases respectively.

Bulgaria participated in the EUROASPIRE V study to determine whether the joint ESC–European Society of Hypertension guidelines on secondary cardiovascular prevention are followed in everyday practice (*47*). The study of 28 countries found that many patients with coronary heart disease have unhealthy lifestyles, with persistent smoking and weight-related dietary factors, including sedentary behaviour, and that despite the high use of cardioprotective drug therapies, most patients did not achieve their blood pressure, low-density lipoprotein cholesterol and glucose targets. The specific results for Bulgaria were not seen.

Rapid response and secondary care after AMI and stroke

Functioning clinical networks for ACS, stroke, heart failure or other cardiac disease do not exist (*48*): see *Challenge 7* for further information. There are 56 catheterization laboratories performing primary percutaneous coronary interventions (PCIs) 24 hours a day, seven days a week, unevenly distributed in the regions of the country; almost half of them are owned by private companies. Comparing 41 European countries for which data were available, the ESC Atlas reported Bulgaria to have the second-highest rate (6.0) of coronary intervention centres per million people, close to the rate for Germany (6.6 per million population). It also found Bulgaria to have the third-highest rate (168.2) of cardiologists per million people in 2014, compared with an average in Europe of 86.3 (and median 72.8) per million population (*49*). The proportion of interventional cardiologists in Bulgaria is also high: 19.38 per million population (mean 11.8 and range 1.97–30.96 for the 33 European countries for which data were available).

The rate of primary PCI in Bulgaria rose from 21% in 2008 to 56% in 2011, and the proportion of ST-elevation MI (STEMI) patients receiving no reperfusion fell from 63% to 36% in the same period (*50*). According to the ESC Atlas, the rate of PCIs per million people in 2014 was 3603 in Bulgaria, second only to Germany (3975) in 41 European countries (average 2211 per million) (*49*).

There are 48 hospitals that in 2019 have performed thrombolysis to at least one stroke patient, but only 18 hospitals are regularly providing systemic thrombolysis for acute stroke and have treated more than 20 patients. Nevertheless, the coverage of the country in term of hospitals providing reperfusion treatment is suboptimal. The rate of the recanalization procedures for stroke patients in the country is relatively low compared with most European countries and

disease burden; considering that the total number of estimated stroke patients is 20 000 per year, the rate from 2014 to 2018 was between 1.35% and 3.9% (*51*). In 2018, 12 of the 28 regions of the country (Burgas, Dobrich, Lovech, Montana, Pernik, Razgrad, Sliven, Smolyan, Sofia, Stara Zagora, Veliko Tarnovo and Vratsa) had no hospitals that had provided reperfusion treatment to at least five or more stroke patients for the whole year.

Performance monitoring of the proportion of people with AMI or stroke who receive medical assistance within target timeframes does not take place routinely. Time of admission/discharge to hospital is recorded but times to intervention are not routinely noted and there are no national registers for ACS or stroke. A 2009 study (*46*) conducted in the Stara Zagora region found that for all AMI inpatients, STEMI and non-STEMI, the median pain-to-door time was 3 hours and 15 minutes. For STEMI inpatients, the median time was 3 hours (mean 4:32 ± 4:25). Around 28 centres independently enter data into the international stroke registry (RES-Q) and achieve a mean door-to-treatment time of 55 minutes.[6]

This topic is further described in *Challenge 7*.

3.2.2 Diabetes

Table 6 shows the assessment of implementation of individual services for diabetes prevention and management.

Table 6. Score card for individual services for diabetes prevention and management

Intervention	Rating	Criterion for rating
Effective detection and general follow-up	**Moderate–Extensive**	A systematic approach is used for screening for diabetes: those at high risk of diabetes are identified using the FINDRISK tool. WHO estimates that 7.6% of adults have diabetes (fasting blood glucose was not measured in the national NCD risk factor survey 2014). Proportions that are detected in PHC (observed/expected) are not known. A national register exists but is not actively used. Active use of a register of adult patients with diabetes in PHC seems variable although it is possible to generate a list from electronic records. Patients can see a GP four times per year or endocrinologist two times per year within the national contract/clinical pathway: this may not match clinical need or focus on achieving better outcomes.
Patient education on nutrition, physical activity and glucose management	**Moderate**	The GP contract includes payment for prevention/health promotion. GPs do not seem to have received specific training in this area; the nature and quality of what is done by GPs are unknown. No one else in PHC is available to provide therapeutic patient education or organized dietary counselling. The NCPHA produces and disseminates materials to support patient education. The NHIF pays for two glycated haemoglobin (HbA1c) tests per year according to clinical pathways; it should be possible to estimate the proportion of registered diabetics that have been tested in the past 12 months.
Hypertension management among diabetic patients	**Moderate**	Blood pressure in diabetic patients is apparently routinely checked. No information is available about detection or achievement of blood pressure control among diabetics. In principle, it may be possible to get data from some PHC information technology systems but this is not routine.
Preventing complications	**Moderate**	No information exists about prevention of complications or coverage at the national or PHC levels. People with diabetes are offered appointments with ophthalmologists and neurologists once per year; no overview exists on uptake or outcome. Nor is there an overview of prevention of complications. Trends in, for example, amputations and blindness among those with diabetes are not routinely monitored.

[6] Data from the RES-Q registry: 10 800 patients from 28 centres

Effective detection and general follow-up

Bulgaria does not have an active national diabetes register. A national working group was appointed to set one up in 2014 but by 2018 it was still not functional (*52*). Up-to-date national figures for prevalence of diabetes in the general population are not available: fasting blood glucose was not measured as part of the most recent national NCD risk factor survey in 2014. The International Diabetes Federation estimated that there were 424 300 cases of diabetes in Bulgaria in 2017 and an adult population prevalence of 7.9% (*53*). The WHO age-standardized estimate was similar, giving the prevalence of diabetes mellitus in Bulgaria in 2014 as 7.6% (males 8.4%; females 6.9%) (*54*). There may be a significant underdetection rate for diabetes: the number of cases detected through screening as part of preventive medical examinations appears to be much lower than what would be expected based on the estimated prevalence levels for the general population.

A systematic approach is used for screening for cases of diabetes: those at high risk of diabetes are identified using the FINDRISK tool. Risk factors assessment for the development of type 2 diabetes mellitus establish that 110 224 people have moderate risk based on FINDRISK, 42 512 people have high risk and 2629 people have very high risk. A blood glucose test is administered when the following risk factors have been identified: hypertension; dyslipidaemia; obesity; family history of diabetes mellitus – first-degree relatives with diabetes mellitus (parents, siblings); a history of diabetes during pregnancy or a birth to a baby weighing more than 4 kg; and a history of polycystic ovarian disease. A blood glucose test may also be performed if other CVD risk factors are found.

In case of doubt about diagnosis associated with diabetes, the GP may want to refer the patient to the specialist. When following up a patient with recently diagnosed disease, or when diabetes complications occur, the GP has the right to appoint a highly specialized examination such as microalbuminuria monitoring for diabetes.

Routine monitoring of patients with diabetes is carried out by GPs and endocrinologists. In principle, it seems to be possible for a PHC doctor to generate a list of diabetic patients from electronic records although it may not be routinely done.

Every quarter, the GP obtains a specific number of referrals for examinations and consultations. These referrals represent a voucher with a monetary equivalent that may be "cashed" in a medical laboratory or by a specialized healthcare provider (specialized outpatient care, specialist working through the NHIF system), e.g. endocrinologist, oncologist, etc. As the number of referrals is limited, a common practice is to reach its limit before the end of the quarter. According to the GP contract, the NHIF pays for the follow-up by GP four times per year, or according to clinical pathways by endocrinologist two times per year: this may not match to clinical need or focus on achieving better outcomes. The costs for insulin and metformin are fully covered.

Patient education on nutrition, physical activity and glucose management

The GP contract includes payment for prevention/health promotion. GPs do not seem to have received specific training in this area; therefore, the nature and quality of what is done by GPs are unknown. In general, no one else in PHC is available to provide therapeutic patient education or organized dietary counselling at an individual patient level. A nurse may share a room with a doctor and use it for consultations. In any case, the doctor needs to be present if the nurse counsels a patient with hypertension or diabetes.

The NCPHA produces and disseminates materials as guidance and for patient education. The regional branch that the assessment team visited had a health education counsellor who was available to organize campaigns and counsel patients. There did not seem to be referral pathways from general practice to these centres. Family nurses do not appear to carry out patient education/counselling routinely.

A cross-sectional study on care of type 2 diabetes mellitus in Bulgaria and neighbouring countries found that routine measurement of HbA1c was infrequent (less than 50% of patients at baseline) and that in Bulgaria, specialists measured it as rarely as GPs (*55*). When it was measured, glycaemic control was found to be poor and did not differ significantly between specialists and GPs. The NHIF pays for two HbA1c tests per year according to clinical pathways. Figures on uptake were not available at the time of the mission.

Structured diabetes education seems to be rarely offered to people with diabetes according to a 2014 report (*56*). Diabetes education is not covered by compulsory insurance and depends on associations as well as the commitment and workload of individual doctors.

The Bulgarian Diabetes Association was created in 1990 by a group of endocrinologists, doctors and patients to improve the way of life, medical care and prevention of complications to people with diabetes in the country (*57*). It is the only nationally representative association for patients with diabetes in Bulgaria (*53*). It has been very critical of the quality of diabetes care in Bulgaria, commenting that NHIF funding is allocated for "hospital treatment, amputations, dialysis and surgeries due to delayed and inadequate treatment, rather than supporting prevention, self-management and education" (*56*). The Euro Diabetes Index 2014 report ranked Bulgaria at the bottom among 30 European countries in terms of quality of diabetes prevention and care (*58*).

Diabetes medication is fully covered by public funds for the health insured, although not antihypertensive medication or statins for people with diabetes. Patients with insulin-dependent diabetes are provided with 180 test strips per year to use with a glucometer, and a patient with gestational diabetes is provided with 1000 test strips per year.

Hypertension management among diabetes patients

Blood pressure in diabetic patients is apparently routinely checked. There is no overview of the extent/quality of detection or achievement of blood pressure control among diabetics. In principle, it may be possible to get data from some PHC information technology systems to assess this, but this is not routine. Antihypertensives and statins are not fully reimbursed, even for people with diabetes.

Prevention of complications

Trends in, for example, amputations and blindness among those with diabetes are not routinely monitored, and effectiveness in preventing complications is not known. The number of amputations per year and the number of people with diabetes who are registered as blind were not available, nor was the number of complications.

Diabetes specialist nursing is not recognized as a speciality. Nurses involved in diabetes care receive ad hoc training once employed in a department offering such care. It was reported that their role in diabetes care remains limited.

According to the clinical pathway, people with diabetes can be offered appointments with ophthalmologists and neurologists once per year but there is no overview of uptake or outcome. In practice, it seems that eye examinations are rarely offered to people with diabetes until complications have already developed. Eye screening and care services were reported to be available mainly in the major cities. Due to the limited information available to people with diabetes and limited financial coverage by compulsory insurance providers, affordability and awareness issues were reported both by stakeholders and in literature assessing access to eye screening and care.

Podiatric care remains limited and countries such as Bulgaria and Croatia only provide foot care on a private basis.

Cancer prevention and screening

The framework of the National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 and its Action Plan describes screening activities for various types of cancer. Screening is also carried out through numerous initiatives throughout the country. However, apart from the prevention of NCD risk factors, there is only one national cancer prevention programme, specifically the National Programme for Primary Prevention of Cervical Cancer 2017–2020. Its strategic goal is to immunize girls aged 12–13 years, to achieve reduction in cervical cancer's morbidity and mortality in the country.

The Ministry of Health is working to improve annual health check-ups as a prophylaxis programme and there are ordinances establishing the screening policy for three types of cancer (cervix, breast and colorectal). Screening in asymptomatic populations is under the coverage of the NHIF. Nevertheless, early diagnosis of cancer is not even otherwise considered as part of any strategy for NCDs or cancer control.

Table 7 shows the assessment of implementation of individual services for cancer prevention, early detection and management.

Table 7. Score card for individual services for cancer prevention, screening and management

Intervention	Rating	Criterion for rating
Prevention of liver cancer through vaccination against hepatitis B	**Extensive**	Hepatitis B vaccine has been a mandatory part of the immunization calendar for newborns since 1992. The vaccine is provided free of charge and coverage is high (> 90–95%).
Vaccination against HPV	**Limited**	Vaccination against HPV started in 2012 for girls aged 12 years and in 2015 included 13-year-old girls. It is free, but not mandatory. Initial coverage was at 30%. Current coverage fell to less than 7% (due to an anti-vaccination movement).
Screening of cervical cancer and treatment of precancerous lesions	**Moderate**	An ordinance established the screening policy: clear and correct criteria for target population (age to screen), frequency of screening and test to use (Pap smear). Screening is free of charge. There is no clear policy for follow-up. No monitoring and evaluation is conducted. Coverage is not known. Impact on stage at diagnosis, incidence and mortality is not known. Treatment is free and accessible.
Early case-finding for breast cancer and timely treatment of all stages	**Moderate**	An ordinance established the screening policy: clear and correct criteria for target population (age to screen), frequency of screening and test to use (mammography). Screening is free of charge. There is no clear policy for follow-up. No monitoring and evaluation is conducted. Coverage is not known. Impact on stage at diagnosis, survival and mortality trends is not known. Treatment is free and accessible.
Population-based colorectal screening at age > 50 years linked with timely treatment	**Moderate**	An ordinance established the screening policy: clear and correct criteria for target population (age to screen), frequency of screening and test to use (faecal occult blood). Screening is free of charge. There is no clear policy for follow-up. No monitoring and evaluation is conducted. Coverage is not known. Impact on stage at diagnosis, incidence and mortality is not known. Treatment is free and accessible.

Prevention of liver cancer through vaccination against hepatitis B

The hepatitis B vaccine has been included in the national immunization programme since 1992. The vaccine is a mandatory component of the immunization calendar for newborns. Vaccination is cost-free. Although coverage was higher 10 years ago, during the past years it has been stable at around 95%. The impact on the incidence of hepatitis and on liver cancer has not been evaluated yet.

Vaccination against HPV

HPV vaccination started in 2012 for 12-year-old girls, with three doses and reached coverage of 30% among this population in the starting period. There was an incident with a vaccinated girl who died under unclear circumstances. This situation was utilized in a big mass media attack. The Ministry of Health created a working group to study the case. The cause of death was clarified and no link between the fatality and the vaccine was proven. Nevertheless, the negative media harmed the vaccination programme. Coverage fell to only 2% in subsequent years. In 2015 the programme was redesigned to include girls aged 12–13 years and followed the international recommendations using only two doses. The vaccination is free of charge, but it is not mandatory. Coverage started to increase but remains very low at 5–7% among 12-year-old girls and 1–3% among girls aged 13 years. All these circumstances seem to affect the enthusiasm of the Ministry of Health professionals involved in this programme as there is not an active and organized plan to promote HPV vaccine in the country.

Screening of cervical cancer and treatment of precancerous lesions

The Ministry of Health screening programme/ordinance establishes the screening policy, but in general the screening is not well organized and there is no expert group at the Ministry of Health to coordinate the screening programme. Cervical cancer screening (Pap smear) is performed by gynaecologists and GPs at PHC level. There is no participation of midwives or any other health professionals.

Although the ordinance defines a clear target population (age to screen) and the interval/frequency of the screening, there is no well-defined policy for the follow-up of suspicious or positive cases. There is no accurate information on coverage as there is no monitoring and evaluation system in place and, consequently, no monitoring and evaluation is conducted or even planned. Screening is free of charge and fully covered by the NHIF. Due to the lack of information, the impact on changes on the proportion of the stage at diagnosis and cancer incidence expected after the implementation of cervical cancer screening is not known, and there is no analysis of the impact on mortality that this screening has and the cost–benefit of this action. Cervical cancer screening falls under the responsibility of GPs and gynaecologists without coordination by the regional health authorities. Access to treatment of cancer patients is also free of charge. There are cancer treatment services all around the country, which make surgery, systemic treatment and radiotherapy (including brachytherapy) accessible to patients, but there is no linkage between the screening and the treatment centres.

Early case-finding for breast cancer and timely treatment of all stages

There has been a screening programme/ordinance from the Ministry of Health since 2011 establishing the breast cancer screening policy, advocating breast mammography screening for women over 50 years every two years. Nevertheless, in general, screening is not well organized in practice and there is no expert group at the Ministry of Health level to advise and coordinate the screening programmes. The ordinance defines clearly and with correct criteria the screening target population (age to screen) and the frequency/interval of screening. Breast cancer screening (mammography) is performed in facilities where the equipment is available; there are no specially designated units with trained personnel on screening. The volume of mammography studies per centre or machine, in the visited facilities and according to the personnel interviewed, is low and without waiting list for the procedure. There is no clear policy for the follow-up of suspicious or positive cases and no information on the final diagnosis. The screening is free of charge, but no monitoring and evaluation is conducted; therefore, there

is no accurate information on the coverage and its impact on stage at diagnosis, survival and mortality trends is not known. Although screening, diagnosis and treatment are disconnected, access to cancer management (diagnostic confirmation and treatment) is accessible for patients. Surgery, systemic treatment (including costly medicines) and radiotherapy if needed are free.

Population-based colorectal screening at age > 50 years linked with timely treatment

As for the other two cancers mentioned above, the Ministry of Health has a screening programme/ordinance establishing the screening policy for colorectal cancer. However, in general, screenings are not well organized and there is no expert group at the Ministry of Health level to advise and coordinate the programme. The ordinance defines clearly the target population to screen, the test to be performed (faecal occult blood) and the interval/frequency of the screening; there is no well-defined policy for follow-up of suspicious or positive cases. In these cases, a colonoscopy should be performed. There is no waiting list for that procedure and – as for other cases with screening test positive or suspicious – there is no clear policy for the follow-up or information on the final diagnosis. Screening is free of charge, fully covered by the NHIF, but there is no system to collect information for monitoring and evaluation. Although the NCPHA runs the Bulgarian National Cancer Register, the information collected does not allow it to monitor and evaluate the screening programmes. Therefore, coverage is not known and the expected impact on reduction of late stage at diagnosis, the reduction on cancer incidence (expected after the implementation of colorectal cancer screening) and the reduction on mortality are not known. Surgery, systemic treatment (even with expensive medicines) and radiotherapy when needed are available and accessible.

Screening for other cancers

Since 2011, the screening policy has included a prostate-specific antigen blood test for prostate prevention cancer for men over 50 years of age. This has been introduced as part of the annual health checks for insured persons. There is no organized screening for other cancers. Of interest is the situation of human resources for early detection. For both components – early diagnosis and screening – the role of health professionals at PHC level is crucial.

4. Health system challenges and opportunities to scale up core NCD interventions and services

This section reviews the health system features that influence the control of NCDs. Fig. 6 summarizes the common features.

Fig. 6. Common health system features for NCD control

Political commitment to NCDs	Explicit priority-setting approaches	Interagency cooperation	Population empowerment
Effective model of service delivery	Coordination across providers	Regionalization	Incentive systems
Integration of evidence into practice	Distribution and mix of human resources	Access to quality medicines	Effective management
Adequate information solutions	Managing change	Ensuring access and financial protection	

Source: WHO Regional Office for Europe (*4*)

Challenge 1. Political commitment to NCDs

Bulgaria demonstrates political commitment to the global NCDs agenda. The publication "National Health Strategy 2020 and Action Plan" (*59*) encompasses a set of policies to achieve national health goals. Affordable and quality healthcare is one of the targets of the National Development Programme: Bulgaria 2020 (*60*) and the National Strategy for Demographic Development 2012–2030 (*10*). Health is thus considered as one of the factors for economic growth.

The concept paper "Objectives for Health 2020" (*61*) puts NCDs as one of the priority actions, the National Development Programme: Bulgaria 2020 mentions NCDs as challenges, and CVDs and cancers are among the main policy directions of the National Strategy for Demographic Development 2012–2030.

The National Health Strategy 2020 builds upon other main strategic national and European policies, such as the National Reform Programme, the National Strategy for Reducing Poverty and Promoting Social Inclusion 2020 and the Europe 2020 strategy. According to the National Health Strategy 2020, the main challenges Bulgaria faces are related to the deteriorated indicators of the health-demographic status of the population, the existence of health inequalities and the need for a national health system to respond adequately to the needs of accessible and high-

quality health services. To address these challenges, the National Health Strategy 2020 defines three main priorities for actions: (i) creating conditions for better health for all throughout the life-course, (ii) strengthening and managing a fair, sustainable, high-quality and result-oriented health system and (iii) strengthening public health capacity.

The National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 (*62*) provides the overarching framework to tackle NCD risk factors and promote early diagnosis. It is funded from the national budget. The Programme is an integrated approach to reducing premature mortality, morbidity and related health consequences. It includes monitoring and evaluation frameworks, timeframes for implementation and target indicators. It was planned on the experience of the Countrywide Integrated Noncommunicable Disease Intervention (CINDI) project, which ended in 2010.

Other policy documents that provide a platform to address NCDs are the National Strategy for Children 2008–2018, the National Youth Strategy 2010–2020, the National Long-Term Care Strategy, the National Programme for the Prevention of Oral Diseases in Children 2015–2020, the National Programme for Primary Prevention of Cervical Cancer 2017–2020 and the Food Act, among others (*63*).

Challenge 2. Creating explicit processes for setting priorities and limits

Prevention of NCDs may be relatively under-resourced compared with communicable diseases. Funding is primarily provided by the state budget and distributed through national programmes and local action plans, the latter co-funded by the municipalities. Only 2% of the current budget is allocated to NCDs compared with the 18% assigned to communicable diseases programmes. In addition, the NHIF pays for some primary prevention of diseases and early detection provided by primary care practitioners.

Allocation of funds is based on programmes rather than needs and priorities. The budget is based on historical patterns and existing investment rather than on health needs and priorities. The Ministry of Health funding is implemented through a programme budget, which includes programmes focusing on the three main policies: health promotion, prevention and control; diagnostics and treatment; and medicines and medical devices.

In 2017, health expenditures represented 8.1% of the gross domestic product (GDP), compared with the 9.8% EU average. The level of public financing is steady at around 52% of total health expenditures (*64*). Except for Slovenia, Bulgaria spent more on health as a percentage of GDP than all Member States that joined the EU after 2004 (*65*). Although both public and private health expenditure contributed to the increase of total health expenditures, the growth rate of private expenditure outpaced that of public spending. Meanwhile, the National Household Budget Survey indicates high levels of expenditure on health (5.4% of the household budget in 2017), in addition to the social insurance contribution (*66*), which restricts significantly financial protection (see *Challenge 15*).

There are some efforts to reduce inequalities in vulnerable and minority populations. The Ministry of Health, through the NHIF, provides for vaccines and all activities related to immunization, and funds for non-insured individuals including comprehensive dispensary care for dermatological and sexually transmitted diseases and mental health conditions; all women without health insurance; and those in need of acute care. There are also regulated mechanisms that aim to respond to inequity in terms of the distribution of NCD risk factors across different socioeconomic groups. A recent example of governmental commitment is the National Roma Integration Strategy 2012–2020. There is also a public council of the Centre Fund

for Treatment of Children and the Commission on Rare Diseases, established at the Council of Ministers to provide financial support to children with rare diseases or in need of treatment abroad. The concept paper "Objectives for Health 2020" highlights care for vulnerable groups as one of its priorities, which includes people who are illiterate; from minority groups; long-term unemployed; experiencing social isolation and economic dependence; refugees; victims of human trafficking, domestic and other violence; have family members with alcohol and other addictions; and patients with mental illness. It suggests establishing a health mediator at municipal level as a working model to overcome cultural barriers.

Challenge 3. Strengthening interagency cooperation

The government has taken steps to mobilize multisectoral or whole-of-government action on health. The Ministry of Health interacts with all ministries with a direct or indirect relevance to population health, especially in the development and implementation of strategies and programmes. There are permanent cooperation bodies such as national councils, interagency councils, advisory councils, expert groups and working groups.

The National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 is based on interagency work. It promotes intersectoral cooperation through the development of coordinated, collaborative activities, as well as an integrated multidisciplinary approach at interinstitutional level under the leading and coordinating role of the Ministry of Health. Programme management is carried out by a council led by one deputy minister of health and includes representatives of different ministries, as well as the NHIF, NCPHA and Bulgarian Medical Association. Box 1 shows an example of cross-sectoral collaboration.

Box 1. Example of cross-sectoral collaboration

The Health Partnership initiative was established in 2015 and is chaired by the Minister of Health. Its main objectives are: to achieve broad public consensus and cooperation in the implementation, monitoring and evaluation of health policies; to improve coordination and interaction between all government bodies, local government bodies and nongovernmental organizations (NGOs) in the field of health in developing and implementing strategies and programmes of national and international importance; and to enhance synergies to improve public control over planning, implementation and effectiveness in spending public funds on health.

Bulgaria has NGOs that implement projects to prevent CVDs, stroke and type 2 diabetes, and address modifiable behavioural and social risk factors, particularly among people aged over 65 years. These NGOs include public health associations, patient associations (Roma community, chronic diseases, disabilities), organizations to protect patients' rights and a national support network for older people, composed of 47 NGOs.

Challenge 4. Population empowerment

Bulgarian citizens have free choice of health provider (GPs, specialists, diagnostic laboratories or hospitals), with no territorial restrictions according to the Health Insurance Act and the Health Act. GPs can be changed twice per year. There are some administrative restrictions – patients need to be directed by their GP or by a medical specialist who has a contract with the NHIF. Once hospitalized, patients have the right to choose a doctor or a team at extra charge. Despite these prerogatives, patients may find themselves restricted to exercise them due to the uneven variation in distribution of health providers across the country.

Patients lack access to information to make informed decisions. According to the National Health Strategy 2020, one of the weaknesses of the health system is the insufficient awareness of the population regarding their rights and the obligations of the stakeholders of the health system – patients, health facilities and financing institutions. In 2009, the Public Council on Patients' Rights with advisory capacity was set up at the Ministry of Health. Stakeholders organize a range of activities to provide populations with information related to health and the health system. The NHIF is obliged to provide to insured individuals information about health facilities and pharmacies with which a contract has been signed, as well as about patients' rights, the package of services guaranteed and the overall provision of health services.

A mechanism for public participation in the management of the health system exists but in practice its functioning is limited. According to the Health Act and the Health Insurance Act, health-insured individuals participate in the management of the NHIF, yet the management body currently has just one such representative. At local level, the public is represented in municipal councils and health commissions. The Ministry of Health has involved patients' organizations in the process of policy development. In most cases, this is done on an ad hoc basis and by initiatives of the single working groups. The media plays a particularly active and supporting role in this process. However, participation is often limited to discussions on specific legislative or organizational changes to the latest stage of the development process.

Some NGOs and associations such as Open Society Institute – Sofia, the Bulgarian Chamber of Commerce and Industry, medical universities and others are conducting research on patient satisfaction, public awareness and other health issues, providing strong evidence to support development and implementation of health policy. At the same time, there is no evidence that policy-makers use these results in defining health priorities.

Patients may lodge complaints with different institutions at the national and subnational levels, such as the Ministry of Health's Executive Agency Medical Audit, RHIs, the NHIF and its regional branches but also with professional associations. The Executive Agency Medical Audit controls providers regarding quality, patient safety and patients' rights.

Health literacy is relatively low. Bulgaria was one of the eight European countries participating in the European Health Literacy Survey in 2011 and was found at the time to have the lowest mean health literacy score (*67*). Almost two thirds of the Bulgarian population were found to have inadequate (26.9%) or problematic (35.2%) health literacy. A number of programmes have been put in place since then to improve the situation (*68*). Sporadic events are used to raise awareness. Often organized in the framework of celebration of "world days", for example World No Tobacco Day or Month of Sobriety, they may include: lectures, discussions, pieces of training, screening campaigns, television and radio broadcasts, audio and video clips, videos, exhibitions, quizzes, theme days, health celebrations, sports competitions, contests, campaigns and distribution of printed materials. Informational health-related leaflets are available in health facilities but facilities for health counselling are limited (see *section 3.2*).

Challenge 5. Establishing effective models of service delivery

The public health system of Bulgaria has structures in place to carry out core functions of NCD prevention, control and surveillance. Public health in Bulgaria is coordinated by the Ministry of Health. Primary prevention policies are brought together, developed and approved by the Ministry of Health and organized, coordinated and implemented by the 28 RHIs (local branches of the Ministry), in collaboration with local governments that remain jointly accountable. RHIs provide services such as inspecting establishments for adherence to smoking bans, health education and tobacco cessation support. The public health system includes several national centres involved in the protection and promotion of public health,

namely the NCPHA, the National Centre of Radiobiology and Radiation Protection and the National Centre for Addictions. The NCPHA has a significant role in NCD prevention, for example, through assessing the impact of environmental and other risk factors on health, designing and implementing programmes for health promotion and disease prevention, providing information on health status in the country and running the National Cancer Register.

The GP should have a significant role in NCD prevention and management, and coordination of care, but this is thwarted by a number of factors such as declining numbers and access. The total number of GPs has markedly decreased in recent decades (described further in *Challenge 10*) and regional distribution varies, with numbers low in rural areas (described further in *Challenge 15*). Citizens with health insurance are entitled to change their doctor twice a year, which may also impede continuity of care. GPs perform initial check-ups, diagnosis, treatment and consultation and prescribe medicines in compliance with the Positive Drug List. GPs are also responsible for providing advice on family planning, prevention, immunization, health promotion and health education. According to the Health Care Establishments Act (1999), GPs are the gatekeeper to specialized outpatient and inpatient care. They have also been assigned a key role in provision of preventive medical services, being contracted by the NHIF to provide regular medical check-ups for insured persons over 18 years, and regular follow-up of patients with chronic diseases (dispensaries). The nature of medical check-ups and dispensaries is described further in section 3.2. Approximately two thirds of the total number of visits to primary care is related to diagnosis and treatment, and the remaining one third is for prevention. Nevertheless, the most common violations of the National Framework Agreement in primary care, identified by RHIF inspections, are the lack of provision of preventive services and non-compliance of working hours. The most frequent patient complaints mostly refer to refusal of referrals for specialized medical care or refusal for home visits.

Examples of multiprofile PHC exist. GPs, organized in single or group practices, may employ nurses and other health professionals such as physiotherapists, cardiologists, neurologists, paediatricians and endocrinologists, and may offer laboratory diagnostic services or basic radiology and dental services. Ambulatory care is provided by autonomous, largely private establishments, which are contracted by the NHIF for specialized outpatient care, dental care, diagnostic and consultative services. Some providers may include single or group practices of GPs alongside outpatient and other services.

Although there have been efforts to strengthen primary care, the rate of avoidable hospitalizations is high. Inpatient care is dominant and is delivered mainly through a network of public and private hospitals, divided into multiprofile and specialized ones. Hospital discharge rates due to diabetes, CVDs and respiratory system diseases are among the highest in the EU (*64,69*).

Palliative care is provided in hospices, most of which are private and require out-of-pocket payment. There are standards for palliative care in the ordinance for medical oncology. Although there have been substantial advances in social rehabilitation of cancer patients, country capacity of palliative care is still underdeveloped. Lack of funds for palliative care is the main reason. There are only a few facilities for palliative care in the country. The NHIF covers only a few palliative care activities, e.g. reimburse for a maximum of 20 days admission in the whole year, and this is only in a few centres that are considered to meet the requirements. Although with very limited support, home-based care is an option for end-of-life palliative care patients. GPs can prescribe opioids. Morphine and pain killers are free for cancer patients, but they have to co-pay for other supporting medicines. There is an ongoing training programme on palliative care for GPs. There are only 45 (1079 beds) registered hospices in the country (*70*). Palliative care is provided in a relatively small number of private hospices. For this reason and the fact that there is no additional payment for those services by the NHIF, hospitals do not provide palliative care. Box 2 describes an example of a hospice visited during the assessment mission.

Box 2. Example of a hospice

Hospice Saint John Realsky (Pernik region) is the palliative care centre of a multiprofile hospital. The facility has 20 beds but only half of its capacity is in use due to financial constraints. The Hospice is funded by patient contributions and does not receive funds from the hospital. For bed, food and services the patient is charged 750 leva per month, equivalent to US$ 426; medicines and consumables are charged separately. There are two doctors trained in palliative care, one in rehabilitation, five nurses and four caregivers. Staff are not government employees. During 2018, there were 120 inpatients, of which around 20–30% were cancer patients. Some patients have been staying there for the last five years.

Challenge 6. Improving coordination across providers

In principle, GPs are the key player in the organization of primary medical care but, in practice, their role in coordination of care is constrained. Although GPs are responsible for dispensary follow-up of patients with chronic NCDs such as asthma and ischaemic heart disease, they may not have sufficient competence. Only 70% of GPs have a specialization in general medicine or another medical speciality. The Bulgarian Medical Association is planning to start an online training programme for GPs working in primary care. There are no care managers/coordinators to facilitate the transition of patients. Differences between individual and group practices, lack of interconnectivity among software containing electronic data and lack of incentives towards preventive activities are among the main factors impeding primary care to properly tackling NCDs.

Furthermore, **teamwork among different primary care professionals in primary care is not common practice.** Apart from their practice nurse, GPs seldom collaborate with other professionals such as physiotherapists, community pharmacists or social workers. Multidisciplinary work in primary care is constrained by the limited roles and responsibilities of nurses and social workers. Nurses in primary care are employed by GPs. Although nursing education is advanced (see *Challenge 10*) **the nurses' scope of practice is rather limited, often purely administrative**: nurses in primary care are not involved in caring for diabetics, for example, or providing health education. This is due to the lack of targeted education and specialized training for nurses working in primary care (*71*).

The GP acts as gatekeeper to specialist care (see *Challenge 5*). If the patient's condition requires specialized care, basic diagnostic tests or physiotherapy, the GP refers the patient to the appropriate service "Medical referral for consultation or co-treatment" or, if necessary, for hospitalization. GPs may also refer patients to rehabilitation care in an outpatient or an inpatient setting. The specialists can be co-located in a primary care centre, a private practice or hospital, and patients should be seen within 30 days of referral for outpatient consultation or within days if for inpatient procedure and/or treatment. Insured individuals can choose the provider of specialized outpatient care although the specialists determine the day and time for the consultation. Some regions lack certain specialists, for example endocrinologists, pneumologists, etc.

The limits set by the NHIF for examinations of medical specialists and hospitalizations as well as other contractual factors hamper the effectiveness of inter-level collaboration. GPs have a limited number of referrals to diagnostic tests and specialist consultations. The limit is predefined on a quarterly basis by the RHIF according to the number of individuals in the list, patient characteristics (i.e. type of chronic diseases, age) and the GPs' performance during previous months.

The specialist provides feedback to the GP with indications on the treatment – done through the patient. The patient is given a letter addressed to the GP with the diagnosis, recommendations, prescribed medicines and the appointment for a follow-up visit. It is the patients' responsibility to bring the documentation (discharge letter, tests results, etc.) to the GP after discharge. Despite some providers' use of electronic health records, the information cannot be exchanged with other providers making continuity of care difficult.

Better coordination and planned care might reduce hospitalizations. Inadequate effective outpatient care and lack of collaboration and interaction between outpatient, inpatient and emergency care services have a significant impact on the percentage of hospitalizations. There were not observed structured referral pathways from primary care for patients with chronic NCDs such as stroke or ACS, aimed at managing and preventing complications, optimizing residual abilities and preventing recurrences and hospital readmissions (see *Box 3*). Patients are often re-hospitalized within one year. Many patients are hospitalized for social rather than medical reasons.

Box 3. Stroke management

Patients with stroke are admitted to either a neurologic ward with intensive care including means for respiratory reanimation, or in departments of intensive care or in a stroke unit (*72*). Urgent transportation follows timing standards in Sofia and nearby surroundings.

Bulgaria currently has 133 hospitals admitting stroke patients; in 2019, 48 had performed at least one thrombolysis, and 20 were equipped with stroke units, treating 10% of stroke patients. Hospitals aim to discharge patients in 3–10 days post stroke with a follow-up appointment scheduled a month after discharge. The patient is given a discharge letter. After discharge, there are no structured pathways based on neurological deficit or degree of disability for patients to follow. Information about patient degree of disability, early and late survival after thrombolysis (if performed), and the process of re-socialization is missing (*73*). GPs and hospital specialists may refer patients to inpatient rehabilitation care within 30 days after discharge. A stroke patient can access rehabilitation care, free of charge, once a week four times per year, depending on the pathology and disability.

There is a lack of integration between health and social sectors that is particularly relevant for the provision of services to patients with special and complex needs such as older people, those needing palliative care or for those belonging to disadvantaged socioeconomic groups. Collaboration between sectors is rare, which leads to extended hospital stays and consequent co-payments that further deteriorate the situation of patients. There is also a lack of multidisciplinary work treating cancer patients in hospital.

Challenge 7. Taking advantage of economies of scale and specialization

There is a plan that seeks to rationalize the functions and responsibilities of different healthcare providers. The National Health Map,[7] based on the 28 regional health maps, was introduced in May 2018. The Health Map is a geographical representation of the resources for healthcare in the country. This is further used to plan resources. The Health Map aims at adjusting the healthcare facility network to the needs of the population while ensuring equal access to outpatient, inpatient and emergency care. The Ministry of Health and its RHIs are responsible for its implementation. Hospital care is provided by municipal, regional and national, public and private providers but these are unevenly distributed across the country.

[7] Map or card is used as synonyms for masterplan or just plan.

The aim is that cases are treated in municipal, regional or national hospitals according to their complexity. The classification of the hospitals is made based on the level of competence, staffing, equipment, etc. against the medical standards adopted by Ministerial ordinance.

There has been investment in developing some "high-tech/high-cost" complex interventions. Since 2009, Bulgaria has been a member of the Stent – Save a Life Initiative (*74*) that, for example, supported for several years the establishment of catheterization laboratories. The treatment of cardiovascular and cerebrovascular diseases is carried out in specialized public and private cardiology hospitals and multiprofile hospitals with relevant clinics/wards. The requirements for the treatment are described in relevant clinical pathways, for which the hospital has a contract with the NHIF (see *Challenge 8*). In recent years, there has been enhancement of public and private facilities for invasive cardiology, as well as the provision of modern equipment and staff training. Now, **there is an oversupply of hospitals** and many, even small ones, public and private, can carry out interventional cardiology. Table 8 shows the number of facilities available in Bulgaria compared with European recommendations.

Table 8. Number of stroke units, stroke centres and primary PCI centres in Bulgaria versus minimum standards recommended by European scientific societies

Metric	European recommendations[a]	Bulgaria
No. of stroke units	21[b]	20[c]
No. of stroke centres	7[d]	3[e]
No. of active primary PCI centres	14[f]	56[g]

[a] Based on a population estimate of Bulgaria from 1 January 2020 of 6 925 454 people
[b] Minimum number of stroke units recommended by European Stroke Organisation standards: 3 stroke units/1 000 000, which does not take into account geographical and population density characteristics (2018) (*75*)
[c] Number of hospitals performing thrombolysis and admitting patients to a stroke unit defined as a dedicated environment staffed with a multidisciplinary team, with medical and nursing stroke protocols (2019) (*51*)
[d] Number of stroke centres recommended by European Stroke Organisation standards: 1 stroke centre/1 000 000, which does not take into account geographical and population density characteristics (2018) (*75*)
[e] Number of stroke centres in Bulgaria where thrombectomy is available (2019) (*51*)
[f] Number of primary PCI centres recommended by the Stent for Life Initiative (ESC, 2010) (*76*)
[g] Number of active primary PCI centres (public and private) in Bulgaria

Three regions – Pleven, Sofia and Varna – have centres for endovascular treatment of acute ischaemic stroke; thrombolytic treatment is carried out in a limited number of health facilities. The prerequisite for this development is the availability of equipment and intensive care beds with the possibility to monitor patients during and after the thrombolytic or endovascular treatment, and the availability of trained staff for the implementation of a comprehensive differentiated treatment of ischaemic strokes with the possibility of subsequent endovascular treatment. Nevertheless, **there can be a lack of functional clinical networks for ACS and stroke and comprehensive care including rehabilitation and palliation**. This is described further in section 3.2. Box 4 gives an example of a rehabilitation hospital.

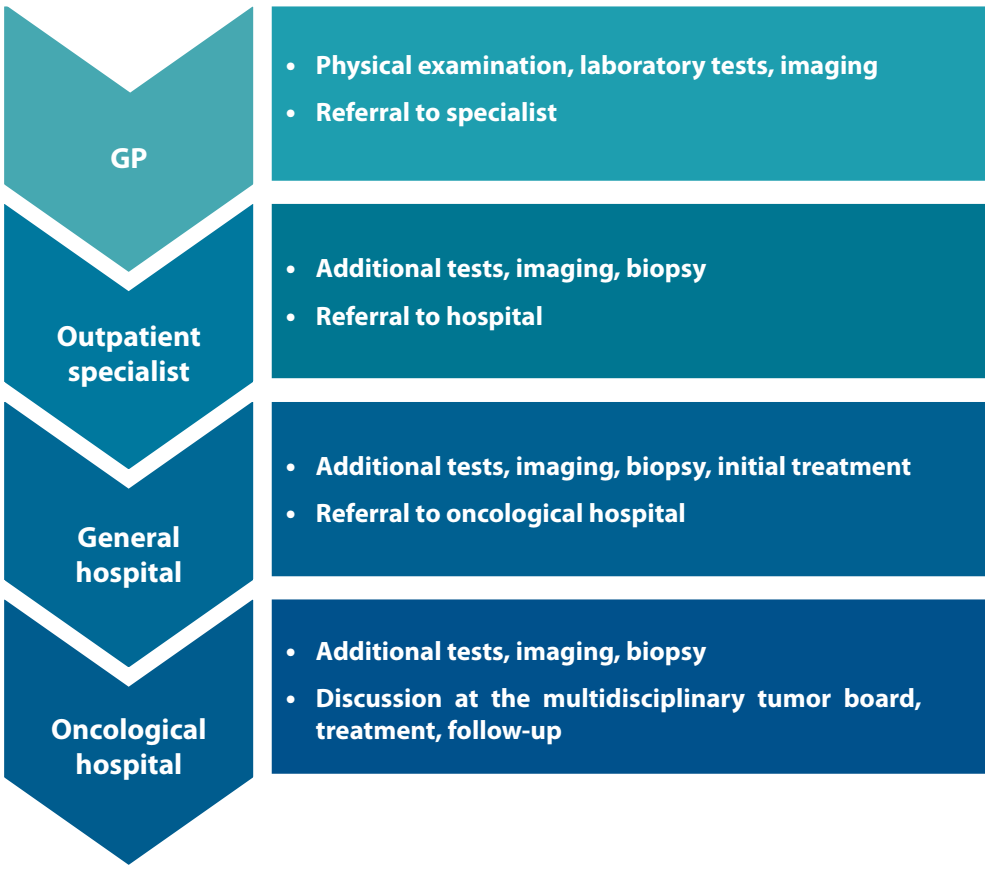
Box 4. Example of a rehabilitation hospital

The *Rehabilitation Hospital*, in Pernik region, specializes in patients who had a stroke and patients with muscle-skeletal sequels of vascular accidents. It was built in 1995 as a rehabilitation facility for neurology diseases such as stroke, Parkinson's, etc. It provides inpatient (1000 patients per year) and outpatient (500 patients per year) services, has 60 beds and 36 staff, including two physiatrists, one internal medicine specialist, one laboratory professional, nurses and physiotherapists. This is the only facility of its kind in the region but due to a lack of funds, only 50% of its capacity is utilized. The authorized length of stay is four days, and the maximum is seven days, twice per year with one-month separation. The cost of the stay is 700 leva per month, equivalent to US$ 398, all-inclusive to be paid by the patient.

A cancer control or care plan does not exist, nor is there an organized network of cancer services. Cancer care is provided in specialized hospitals, complex oncology centres or units of medical oncology, nuclear medicine and radiotherapy within multiprofile hospitals where global standards of research and treatment are applied. Most of the larger hospitals treating cancer patients are teaching hospitals and host residency programmes for different oncology specialities. Most hospitals have diagnostic equipment and modern laboratories, a range of imaging diagnostics such as magnetic resonance imaging, linear accelerators, computed tomography (single photon emission computed tomography (SPECT) and positron emission tomography (PET)) and an automated drug dispensing apparatus. Some hospitals are connected to leading medical centres through remote real-time consultations. These hospitals can diagnose, stage and track patients with all solid tumours. If a hospital does not have a specific service, it has a responsibility to arrange it through other providers and centres/hospitals that receive cancer patients. Usually the referring centre has an arrangement with the receiving centre(s).

Hospital oncology committees with representatives from different specialties design patient treatment plans. For each patient an individual treatment algorithm is developed to provide personalized care. This personal plan determines the type and mode of diagnosis, and therapeutic treatment options with chemotherapy, target therapy, endocrine therapy, conventional radiation therapy, intensive modulated radiotherapy or radiosurgery. The admission of patients is usually scheduled after a discussion by the Clinical Oncology Commission, which sets a diagnostic and therapeutic algorithm for each patient. For example, the decisions for chemotherapy are consistent with the "National Medical Standards for Systemic Drug Therapy, Evaluation of Therapeutic Effect and Traceability of Malignant Solid Tumours in Adults", adopted by the Working Group of the Bulgarian National Association of Oncology and the Pharmacotherapeutic Department of Medical Oncology, approved by the National Council on Prices and Reimbursement of Medicinal Products. The control of the treatment is performed daily by the treating physicians and the head of the relevant structure. The general oncological patient's pathway is depicted in Fig. 7.

Fig. 7. A cancer patient's pathway in the health system



There are initiatives aimed at improving emergency medical care. The Concept Note for the Development of the Emergency Medical Care System 2014–2020 (*77*) was consolidated in the National Health Strategy 2020 and operationalized in medical standards. It introduces a triage system, time limits for the execution of emergency calls, protocols and algorithms of behaviour concerning emergency patients, and the composition and the professional competencies of members of the emergency teams (as mobile and stationary teams may be supplemented by professional specialists – paramedics). The Ministry of Health has invested to modernize the ambulance vehicles and equipment, as well as provided opportunity for remote consultations (telemedicine) through the Operational Programme "Regions for Growth" 2014–2020. Funded under the Operational Programme "Development of Human Resources" 2014–2020, the Programme "Improving conditions for treatment of emergency care cases" provides and enhances professional training of emergency medical care staff. There is a well-established curriculum for the specialty, and the specialization is regulated by an ordinance of the Ministry of Health, carried out only in accredited medical institutions. Despite these efforts, the emergency medical services do not have specific protocols or receive instructions on where to bring the patient in case of suspected stroke or ACS. In general, it is thought that transportation time is less than 120 minutes from anywhere in the country to a relevant facility; the ambulance decides where to take the patients.

Challenge 8. Creating the right incentive systems

Current provider payment schemes (incentives) do not lead to a health outcome-oriented model of care. The payment to providers focuses mainly on episodes and cases rather than health outcomes.

Public health activities carried out by the RHIs are directly funded by the Ministry of Health on a historical basis.

GPs are mainly funded per capita by the NHIF based on the National Framework Agreement. Additionally, GPs receive fee-for-service payments for prevention activities, for working in remote areas or under unfavourable conditions, and for examining individuals from other regions, or those uninsured or not included in their list. GPs also receive a fixed user fee per visit.[7] GPs charge an additional fee for activities not included in the NHIF package, e.g. issuing a medical certificate. There are no clear financial incentives to promote patient education and support groups for prevalent conditions or to encourage coordination with social services. According to the NHIF there are GP vacancies and also GPs that serve too many patients as there is no limit to the number of patients enrolled in the GPs' lists. This type of payment scheme fosters GPs to refer insured patients to specialized care.

Specialized outpatient care and laboratory services are paid on a fee-for-service basis. Providers of specialized outpatient care receive payment also for preventive check-ups of persons included in child and maternal health programmes and persons over 18 who are part of specific risk groups. Specialists receive a fixed user fee per visit.[8] This payment scheme encourages a high volume of unnecessary diagnostic tests and visits.

Hospitals receive funding in a case-based scheme (so-called clinical pathways). In 2017, there were 267 clinical pathways. Clinical pathways are paid at a defined fixed price negotiated between the NHIF and the Bulgarian Medical Association. The payment includes spending on clinical interventions, ancillary services and two outpatient check-ups after discharge. The

[8] Thirteen patient groups including children, chronic patients, pregnant women and others are exempt from paying user fees.

"price" assigned to the clinical pathways reflects the ability of the NHIF to pay rather than the real value of the hospital services. So, for example, the care for a patient with AMI, irrespective of the type of treatment, complications and outcomes, is paid for a five-day admission. During the hospital visit, 20–25% of patients stayed longer than five days. In addition, hospitals receive funding for medical devices, but the reimbursement level set by the NHIF for items such as stents/balloons for PCI may not cover procurement cost. Hospitals also collect fixed user fees for each day of stay up to 10 days a year.[8] Given the lack of correspondence between the clinical pathways' prices and their costs, hospitals are encouraged to discharge patients early.

Co-payments for consultations and medicines foster individuals to turn directly to hospitals where medicines and certain procedures are fully covered. This and the incentives for hospitals to admit patients explain the high proportion of hospitalizations, especially related to NCDs. The country led the highest hospital discharge rates in the EU in 2015, with 315 inpatient discharges per 1000 population, rates more than 50% above the EU average (*59*). Experts estimate that around 20% of total inpatient activity could be performed in outpatient settings.

Challenge 9. Integrating evidence into practice

A structured process exists for the development of CPGs, which are developed by national expert boards, and the evidence base is explicit. Each clinical guideline is developed by at least two experts in the field and contains a summarized literature review of the problem. There are recommendations at the end of each section, outlined by the grades of recommendations (A, B, C and D) of the Oxford Centre for Evidence-Based Medicine and good practices. Patient associations or their representatives do not participate in the guideline development process. In principle, new guidelines are incorporated into health professional education and continuing education.

National CPGs do not exist for some of the core services reviewed as part of this assessment. National CPGs for hypertension/CVD prevention, ACS and diabetes do not exist. Cardiologists told the assessment team that they follow ESC guidelines, which are translated and distributed by the national cardiology society. In practice, there are no updated CPGs for management (diagnosis, treatment and care) of cancer patients, resulting in the variability of treatment options and protocols based on the experience of each service and doctors. Treatments are decided based on international guidelines, the type of institution and the experience of the doctor in charge, including when to stop oncology treatment and to start end-of-life or palliative care. Since 2018, a new stroke CPG has been adopted: No. 51: "Diagnosis and treatment of ischaemic brain stroke with thrombolysis". It contains all relevant information, mandatory indications on diagnostic procedure (for example computerized tomography scan about 24 hours after thrombolysis), clinical scales (National Institutes of Health Stroke Scale), minimum hospital length of stay (five days), reimbursement codes for each procedure and a patient information pamphlet. The stroke guideline is published on the website of the national society of neurology.

The relationship between CPGs and prescribing of priority NCD medicines could be further strengthened. Further discussion of this and the Positive Drug List are in *Challenge 11*.

There is a systematic attempt to improve quality of care. The development of CPGs takes place within the context of the national programme of Medical Standards, first adopted in 2001, with subsequent update in 2008. The aim of the Medical Standards programme is to increase the quality and effectiveness of the health system. Standards are established by consensus and approved by the Minister of Health. When developing standards, the following principles are observed: high professional competence; consensus among medical specialists; and direct participation of scientific medical associations, the Bulgarian Medical Association,

the NHIF, medical universities, national centres part of the Ministry of Health and medical establishments for hospital care. For this purpose, a council on "Standards for Quality and Efficiency of Diagnostic and Treatment Services" is set up by the Ministry of Health, which is led by the Deputy Minister and expert working groups for standards development. In addition to developments at national level, there are also standards that are developed locally. Standards have mandatory and optional criteria. Mandatory criteria define the minimum volume related to patient safety, while the optional sets a level that ensures higher quality. For example, there are standards, clinical pathways and orders concerning NCDs; some of them are also published on the Ministry of Health website in dedicated sections. These are not the same as national CPGS.

By an order of the Ministry of Health, General Rules of Good Medical Practice have also been established. These are mandatory for all physicians in the country, and the Bulgarian Medical Association controls their implementation. These Rules were developed in accordance with the Health Act, the Medical Establishments Act and the Professional Organizations Act, recognized international and European experience as well as the specifics of the country. The Rules contain sections on: good medical practice (basic elements, rules, rights and obligations of physicians), teaching and learning, assessment and evaluation of patient relationships, professional relationships, integrity and physicians' health.

Challenge 10. Addressing human resource challenges

Public health capacity for health needs assessment, health planning, monitoring, evaluation and surveillance relevant to NCDs exists, located in the Ministry of Health, national centres such as the NCPHA, RHIs and local authorities (see *Challenge 5*). Nevertheless, such capacity is at risk: specialists in public health have been steadily decreasing from 3341 in 2010 to 2500 in 2015 due to the low remunerations and shortage of young specialists (*78*). The State Health Control Departments of the RHIs face deficiency of physicians and other medical specialists. The Bulgarian Medical Association is currently working on the development of a registry of health professionals that can significantly contribute to better analysis and planning of the health workforce as part of a system of registration and regulation.

There are health workforce shortages for what is needed to prevent and control NCDs: Bulgaria does not have enough GPs and nurses, and other relevant allied health professionals including nutritionists and physiotherapists are few. The share of generalist physicians (which are largely GPs) in the total physician workforce has consistently been decreasing from 21% in 2000 to 16.6% in 2015, which is far below the EU-25[9] weighted average of 30.2% (*65*). Within the group of the generalist physicians, the number of GPs has been steadily going down. Some reasons attributed to this include the heavy administrative workload; insufficient payment and recognition; low appeal of the specialty among young physicians; and problems with training and acquiring the specialty of general medicine (*65*). There has also been outward migration of medical specialists towards other EU countries. According to a change in ordinance, specialist doctors for whom the state paid the specialization now have to remain in Bulgaria for three years after completing their training, and in specific hospitals, specified by the Ministry of Health, where there is a shortage of the specialists concerned. If they do not work for the required three years in these places, the doctors will have to return the amounts paid to the state (*78*). While the number of nurses has stayed comparatively stable during the last 15 years, the ratio of 4.9 nurses per 1000 population is far below the EU-28 average of 8.7. Education of nurses and midwives lasts four years to degree level and can continue thereafter in specific master's programmes and specialist training courses. Many trained nurses emigrate, and this has been attributed to limited career development opportunities and better salaries abroad (*79*).

[9] EU-25: EU Member States as of 1 May 2004

Significant regional inequities exist in the distribution of health workforce. There are regional disparities in the distribution of GPs, resulting in vacant practices in rural and remote areas as well as some GP practices serving large numbers of patients. The distribution of nurses is also characterized by regional inequities. The districts with medical universities and university hospitals attract the largest numbers of physicians and more health professionals on average: in 2017, 22.5% of working physicians worked in the capital and 55.6% were concentrated in six districts. There is also internal migration: one migratory flow is directed from smaller towns to large settlements, and another is from the public to the private sector.

Efforts are underway to redress the balance in numbers and distribution of health workers, and to better manage health worker mobility. A dedicated unit in the Ministry of Health oversees human resources for health and analysis of these data is carried out by the NCPHA, which is also introducing forecasting (*80*). In the context of the Operational Programme "Development of Human Resources" 2014–2020, the Ministry of Health has sought to develop a policy of protection and improvement of human resources in the system by creating more favourable working conditions, better payments, professional training and clear opportunities for career development, security and safety in the workplace. The NHIF provides additional funds to incentivize GPs working under unfavourable conditions. It has been reported that following the change in status from trainee to employee of specialist doctors and abolishment of admission exams to specialist training in 2015, young medical doctors and students of medicine are less interested in emigrating.

Training in NCD-relevant specializations is available for doctors. The Council of Ministers approves the number of undergraduate and graduate student admissions according to the capacity of academies and perceived needs of the professional fields and specialties of the regulated professions. During recent years there has been a tendency to assign more places to medicine than nursing careers. Among medical specialization, the largest shares of physicians are in the fields of anaesthesiology and intensive care and surgery, followed by paediatrics, obstetrics and gynaecology, cardiology, nervous diseases, internal diseases and imaging. Human resources for cancer care are described in Box 5.

Box 5. Human resources for cancer care

Bulgaria has enough specialists in medical oncology, paediatric onco-haematology and radiation oncology, and residency programmes, well-recognized internationally, are available for these specialities. There are 199 medical oncologists, 8 haematologists and 18 paediatric onco-haematologists in the country. These specialists are supported by clinical pharmacists and pharmacologists, psychologists and nurses. There is no specialization for nurses, other supportive professionals and surgical oncologists. Surgeons from different surgical specialities (general surgery, gynaecology, urology, etc.) could treat cancer patients without any specific training in oncology as there is no recognition of subspecialization. In the centres visited, preparation of oncology medicines is done in a centralized area ensuring compliance to requirements for safe handling of hazardous drugs, protecting staff, patients and the environment. Oncology medicines are administered in centralized areas with comfortable chairs and beds.

The Bulgarian Pharmaceutical Union keeps a register of practicing pharmacists in the country, which currently numbers over 6500. Among other relevant tasks such as representing pharmacists and regulating the exercise of the profession, the Union manages the mandatory continuous professional development. These training activities are paid by the participants. Educational activities like webinars, educational material and distance-learning courses are supported by an electronic platform.

Continuous professional development for doctors is not mandatory. The Bulgarian Medical Association registers and coordinates, but does not provide, the continuous professional

development. A credit system is used to assess the medical specialists' performance and recognizes a certain number of credit points for a period of three years.

Professional societies have a role in training and education. For example, during 2018, the Bulgarian Society of Cardiology organized symposia on hypertension, cardiovascular prevention and ACS among others (*81*). National professional associations such as the Bulgarian Society of Cardiology and the Bulgarian Society of Endocrinology are members of the international bodies ESC and the International Diabetes Federation respectively. Health providers and professionals participate in international research and initiatives such as performance benchmarking. Pharmaceutical companies also play a significant role in continuing education (see *Challenge 11*).

Challenge 11. Improving access to quality medicines for NCDs

Bulgaria does not yet have an integrated national medicines policy. The regulatory framework has been largely brought into line with current EU standards; however, the current mechanisms for listing, pricing, prescribing and subsidizing medicines do not ensure value for money. The need to control public expenditure contributes to high out-of-pocket payment, which is likely to prevent access and adherence to treatment.

Medicines represent an important share of the total health expenditure, 38% compared with the EU average of around 25%. The pharmaceutical expenditure per capita (€498 purchasing power standard) was the fourth largest in the EU after Germany, France and Belgium in 2015 (*65*). The out-of-pocket payment is also high, possibly as high as 81% of total pharmaceutical expenditure (*82*). The public coverage for pharmaceuticals in Bulgaria is the lowest in the EU, except for Cyprus (*65*). For further information, see *Challenge 15*.

A Positive Drug List exists, containing potentially reimbursable medicines. The Ministry of Health is responsible for the development, implementation and coordination of national activities related to pharmaceuticals (*65*). The Ministry is supported by the Supreme Council of Pharmacies that advises on priorities, ethical considerations, legislation, research and public campaigns and the National Council on Pricing and Reimbursement of Medicinal Products that sets the maximum retail price of medicines, including the over-the-counter ones, and decides on the Positive Drug List proposed by the Pharmacopoeia Committee. The Positive Drug List includes four annexes (*83*): (i) medicines for outpatient treatment, partly reimbursed by the NHIF; (ii) medicines purchased by public hospitals, emergency care centres, psychiatric hospitals, medical-social centres for children and centres for blood transfusion paid for by health organization budgets; (iii) medicines for the treatment of certain communicable diseases such as tuberculosis and HIV/AIDS, mental and behavioural disorders due to the use of opioids, addiction syndrome, radiopharmaceuticals and vaccines for compulsory immunizations outside the Health Insurance Act, funded by the Ministry of Health; and (iv) ceiling prices for medicines included in the Positive Drug List. Since the end of 2015, a health technology assessment has been mandatory for the inclusion of new medicines (with new international non-proprietary name) in the Positive Drug List (*84,85*). Since April 2019, the National Council for Pricing and Reimbursement of Medicinal Products has overseen the health technology assessment and has issued pharmaco-therapeutic

guidelines. Delegates of the Ministry of Health, the NHIF and the Bulgarian Drug Agency may attend sessions related to the health technology assessment.

The proportion of reimbursement varies yearly according to the NHIF budget as follows: (i) the 100% reimbursement level contains drugs intended for long-lasting treatment of chronic diseases leading to severe impacts on quality of life or disability, including certain oncology drugs, as well as drugs for post-transplant immunosuppression and various orphan diseases; (ii) the 75% reimbursement level applies to drugs intended for the treatment of widespread chronic diseases; and (iii) the rest of the drugs included in the Positive Drug List are reimbursed up to 50%. Therefore, some diabetic drugs in the Positive Drug List are totally reimbursed, such as metformin and insulin, whereas CVD drugs are only partially reimbursed even though patients with CVD are predominantly from socially dependent groups. While medicines are provided free of charge in hospitals, once discharged from hospitals, the usual co-payments apply even if the medicines are needed to prevent a further stroke or myocardial infarction.

In general, the whole population has access to cancer care. Some expensive medicines for hospital treatment of oncological diseases are directly covered by the Ministry of Health. The Positive Drug List includes drugs on the WHO Essential Medicine List, plus other very expensive medicines that still lack enough evidence of cost–effectiveness or impact in overall survival, disease-free survival or quality of life. The situation is coincident with an important limitation of funds for palliative care.

The reimbursement is set as a proportion of the reference price rather than the actual price paid by the beneficiary. The ceiling reference price for the Positive Drug List is determined as the lowest price among eight countries of the EU (Estonia, France, Greece, Lithuania, Portugal, Romania, Slovakia and Spain) and five secondary ones (Belgium, Czechia, Hungary, Latvia and Poland). The reference price is the one used for the reimbursement. In many cases the actual price is many times higher than the reference price; consequently, the NHIF reimbursement represents only a small fraction of the actual price paid. Many medicines for chronic conditions, for which adherence to treatment is important to prevent long-term sequelae or disease progression, carry high co-payments and "premiums" over and above the NHIF's reference prices (*82*). Voluntary health insurance policies are often subscribed for covering the share of the price of the medicines not covered by the NHIF. Often it is cheaper to pay out of pocket the full price of the medicine rather than to pay the fees of a consultation needed for the prescription and the co-payment of medicines (*82*).

Links between the Positive Drug List and CPGs are not explicitly made. There are no explicit links between the listing of medicines in the Positive Drug List and the CPGs and prescribing protocols. There are no officially endorsed pharmaco-therapeutic guidelines despite regulatory provisions stipulating the need of their development and use in clinical practice. This may be related to the utilization of very high-cost, and potentially non-cost-effective, medicines, which is growing rapidly.

There is no mandatory prescription of generics. The prescription of medicines, in ambulatory care and hospitals, is done using commercial rather than the international non-proprietary names. The substitution at pharmacy is not permitted for NHIF-subsidized prescriptions. In case of no availability, the pharmacy, after consulting the prescriber, can substitute the medicine. Originator (brand) medicines are more expensive than generics. This increases the markups of the pharmacies but also the out-of-pocket payment of patients.

The use of generic medicines is declining mainly due to public concerns about their quality. However, there is no evidence for these concerns. Two local pharmaceutical companies produce generics, including those for NCDs. These products are also sold in other EU countries. Campaigns to increase people's trust in generics have been implemented with the support of international partners, including WHO. There have also been efforts to guarantee quality and safety of drugs. The Bulgarian Drug Agency issues licenses and controls the production, use, marketing authorization, wholesale and retail sale, import, safety, clinical testing and advertising of pharmaceuticals, and makes efforts to combat counterfeit pharmaceuticals. Other efforts to improve drug safety include post-marketing surveillance and dissemination of reliable information for patients, for example.

Representatives of pharmaceutical companies are allowed to visit doctors. The promotion materials used are pre-approved by the drug regulatory authority. Pharmaceutical companies also play a significant role in continuing education. They pay for attendance of physicians to conferences, nationally and abroad, support for local projects and some medical trainings. Recently, the Association of Research-based Bulgarian Pharmaceutical Manufacturers (ARPharM) has started a transparency policy communicating outside grants and financial support to physicians and health organizations. As part of the initiative "Transparency Builds Trust", around two thirds of health professionals consent to disclosure of their funding from pharmaceutical companies, and member companies of ARPharM also disclose their financial relationship with medical professionals and health organizations (*86*). This revealed that in 2018, ARPharM invested 29 million leva in training, continuous education and collaboration with health professionals and organizations, of which 17.2 million leva was provided to health professionals (*87*).

Retail trade of prescribed medicines is allowed only in pharmacies, where the prices of medicine are regulated. The Medicinal Products in Human Medicine Act prohibits the sale of prescribed medicines in other retail establishments or on the Internet. There are disparities in the geographical distribution of the pharmacies so small towns without a pharmacy are exempt from the regulation. The Act allows authorized doctors and dentists to sell medicines detailed in a specific list. Over-the-counter medicines can also be found in drugstores.

There are potential incentives for pharmacies to sell the most expensive drugs. Pharmacies are private, do not receive dispensing fees and rely on retail margins. For fully subsidized items, the NHIF pays pharmacies a fixed amount per prescription. Wholesale and retail mark-ups are proportional to medicine prices, which create incentives for pharmacies to stock and dispense more expensive medicines. Retail markups are not applied to fully reimbursed drugs (*82*). The 20% value-added tax adds to the burden of the NHIF and patients. Wholesaler and pharmacy markup varies between 24% and 31% and is established by the Ministry of Health, depending on the manufacturer's or importer's price.

Bulgaria currently has 4203 pharmacies, including those in healthcare facilities, of which 55.3% concluded a contract with the NHIF in 2017 (*65*). Vertical and horizontal integration of pharmacies is not allowed. However, four pharmacy chains had vertical integration with a wholesaler (*65*). Five wholesalers supply more than 80% of the market (*82*). As a consequence, there are groups that are both producer and wholesaler to hospitals and pharmacies and own a pharmacy chain.

Challenge 12. Effective management

An important factor for building a quality and results-oriented health system is the provision of competent operational management in healthcare establishments based on modern methods, technologies and innovations in health management (*59*). State and municipal health facilities have a one-tier management system, and the Board of Directors of state hospitals comprises three people.

There is a well-organized regulatory framework for recruitment of managers. Managers and executive directors of state and municipal hospitals, diagnostic and consulting centres are appointed by the owner for a three-year period following a competitive process (*88*). The process is conducted in three stages: compliance verification with the announced requirements; presentation by the applicants of a proposal for development of the health facility over three years; and interview. There are set criteria for the assessment. The recruitment commission is composed of five persons with at least one qualified as a lawyer and one with a degree in medicine. The decision is published in one national and one local daily newspaper. Applicants to managerial positions can have qualifications in medicine or economics with specialization in health management[10] and at least five years of experience. There is a competitive process also for all the managerial positions of health facilities. Nurses and midwives with the specialty in "management of healthcare" can compete for managerial posts e.g. senior nurse/midwife, chief nurse/midwife.

Managers have autonomy of decisions in their role. Managers are responsible for defining the objectives, identifying the risks, and introducing adequate and effective systems of financial management, accounting policy and information security. Managers are also responsible for the health facility's overall activity, financial results and avoidance of increasing arrears. Their responsibilities include managing the health facility; representing it to third parties; acting as employers for all employees working within it; monitoring its financial situation and maintaining financial stability; making structural and organizational changes; assigning the control of the specific financial situation to the heads of the different structures; organizing its councils/boards; providing information on health activities, resources and analysis of the effectiveness to the owner, to the financing body and to the Ministry of Health; and performing other activities assigned by contracts. Managers are responsible for the quality of the provision of health services.

Standards for sound financial management are in place. There are standards for financial management of state health facilities aiming to achieve sound financial management and to set out general financial principles and policies (accountability and responsibility, adequacy of health needs and economic objectives, efficiency and effectiveness, transparency, sustainability, legality).

There is regular reporting to the Ministry of Health both in terms of health activities and accounting, with feedback on performance. The Minister of Health has established uniform forms of reporting (Unified Electronic Reporting Form) with uniform codes for main indicators and their components grouped under specific characteristics. Accounting is conducted in accordance with the International Accounting Standards, and when they are not applicable, the National Accounting Standards are applied. Health facilities report quarterly to the Ministry of Health through a web-based information system. The health facilities also submit annual financial reports. Hospital management routinely receive timely, accurate information about facility performance to inform their work (see *Challenge 13*).

[10] According to the 1999 Health Care Establishments Act

Challenge 13. Creating adequate information solutions

There is a policy framework and initiatives to create a national health information system building on existing databases and based on individual health records. The intention is for the National Health Information System to unify information systems and health records to follow the patient along the entire path of treatment and aggregate data by 2021. The NHIF and NCPHA, among others, consolidate information from healthcare establishments into national databases. However, there are still fragmented information systems operating between healthcare providers, the Ministry of Health and these institutions.

Healthcare establishments operate parallel information technologies and databases, and exchange data electronically with the NHIF and NCPHA. The latter two institutions (among others) consolidate this information into databases at national level.

Health system data are not oriented towards quality and health outcomes. Health information systems used by health providers and the NHIF are developed for informational and financial control purposes. Output-related information such as waiting times and workloads are effectively produced. Clinical and service quality information is not systematically provided and requires ad hoc analysis.

Hospitals and primary care providers use various NHIF-compliant software to report activity and, subsequently, to receive funding. However, a health information exchange platform that would nurture provider collaboration is lacking, and health data are not systematically collected and processed to measure health outcomes. At national level, there is an action plan and a roadmap for building a new national eHealth system before 2020 (*89*). In 2007, the Ministry of Health launched electronic health records, which have not yet been implemented nationwide; the national health portal was launched in 2008 and the electronic personal ambulatory books – eLAK – in 2008.

Primary care providers use different NHIF-compliant health information systems to store patients' health records, which contain not only primary care activity but also results of examinations and diagnostic tests performed, referrals and medical prescriptions issued by the GP, medicine protocols, epicrisis from hospital treatments, dispensary records and cards from regular medical check-ups. The system does not generate automatic reminders/follow-ups for check-ups or screenings. GPs use these systems for accounting and reporting to the NHIF. The NHIF does not provide feedback to clinicians. Data on morbidity, visits and outpatient care are usually incomplete. RHIs receive annual epidemiological reports of patients that consulted primary care, classified by diagnosis. This enables them to identify needs for specialist services.

Patients do not have access to electronic health records; however, they hold the right to obtain their health information, including hard copies, from health facilities. On the other side, the NHIF has the obligation to provide individuals with access to key information (patient summary) related to their care performed during the last five years.

Hospital management gets accurate information of the health services performed, leading to the possibility to plan and optimize their performance in real time. Hospital information systems allow managers to accurately analyse costs, expenditures and revenues, to monitor workloads, effectiveness, prescriptions of drugs and other medical supplies for every patient's treatment and to monitor bed occupancy rates in general. For instance, Gamma Consult, a hospital information system, provides individual patient records, daily hospital management reports and monthly reporting to the NHIF. A helpful reporting module provides hospital managers with daily activity reports without clinical quality information. Hospital national and regional benchmarking with rankings of top performers is conducted annually in the Best Hospitals initiative (*90*) supported by the Bulgarian Hospital Association (see *Chapter 5*). It provides results on patient and professional satisfaction, hospital management and accreditation.

Few functional diseases registers exist. Registers for diabetes, rare diseases, oncological diseases, etc. were developed during the last decades. However, in practice only diabetes and rare diseases registries are functioning nowadays. The Bulgarian National Cancer Registry and 13 regional cancer registries were established in 1952 (*91*). The Bulgarian National Cancer Registry is based at the former National Oncology Hospital and has had data published in the WHO/International Agency for Research on Cancer Incidence in Five Continents (CI5) series, which is a recognition of its quality. Currently, discussions for the development of registries for CVDs and mental disorders are taking place. The NHIF manages data of clinical pathways for administrative purposes. However, the NHIF data on hospital mortality and morbidity should allow the generation of league tables comparing the performance of different providers.

At population level, there is no risk stratification. Exploitation of the existing data for population health management is missing. Health providers are obliged to collect, maintain, store and provide information both in paper and electronic formats. The volume and type of information is used for building and maintaining NHIF registries. The NHIF is obliged to keep data of insured individuals and data on health providers for the period specified in the Health Insurance Act. The medical documents related to regular check-ups and tests are kept for three years.

Periodic surveys of NCD risk factors take place. A national NCD health risk factors survey was conducted in 2014. The survey that included 3979 individuals, relied on standardized individual interviews based on WHO questionnaires and was previously administered within the national survey in 2007 and in other national studies on nutrition, which allows comparability of results. The questionnaires include: personal data, self-assessment of health status, health information and health behaviour. Personal and administrative data allow exploiting of NCD risk factors disaggregated by key equity parameters. The next national survey is envisaged to be conducted in 2020, which will evaluate behaviour changes due to the activities undertaken by the National Programme for the Prevention of Chronic Noncommunicable Diseases.

Telemedicine is not part of routine practice but has been piloted. Telemedicine pilots have involved foreign institutions on telecardiology – electrocardiogram telemonitoring – as an opportunity to monitor remotely patients with previous myocardial infarction and cardiac arrhythmias (*92,93*).

Challenge 14. Managing change

There is consensus that health system reforms are needed. The public, health policy-makers, health managers and medical specialists have identified changes needed, including in the organization and delivery of care. According to the Bulgarian Chamber of Commerce and Industry, financing, organization, technological and personnel security, regulatory failure and health system effectiveness are main areas of concern (*94*).

There is less consensus, however, on how to proceed. The challenge for the Ministry of Health is to find a balance between those supporting radical actions and those supporting incremental changes, to achieve higher stability and sustainable development of the health system in line with the modern standards applied in the other countries of the EU (*95*).

There are potential risks in implementation such as balancing rights and responsibilities for health: that is, the population relies on guaranteed public access to health services whereas health sector employees rely on fairer, better rewards and higher salaries. In the process of change, serious imbalances and differences may emerge regarding the attitude of the population and healthcare professionals – resistance or support. This imbalance arises and is supported by the lack of strong effective management and lack of systematic control of healthcare activities.

Despite a clear understanding of the opportunities and challenges, and clear policy documents and directions, in practice reforms do not take place. These may be for several reasons. European practice has demonstrated that to overcome the resistance to change and to strengthen the support, an extensive preparation of the public and an adequate professional opinion is needed regarding the objective necessity of certain constraints and more precise regulations of the overall medical care process. Yet, the partial reforms of the health system in recent decades have not been subject to a general concept that brings together the efforts of the state, the employers, the public and the medical personnel to ensure a high health status of the population and respectively a higher quality of life. As a result, structural problems have accumulated for years, leading to the inadequate condition of the health system.

Among the strategies and concepts for improving health and the health system in Bulgaria (*96*) is the Concept Note for Better Health (2010) (*95*). The Concept described the main challenges and set forth a vision for organizational change and sustainable development of the health system. Its main objectives were to end the increasing negative trends and disintegration of healthcare, improve public health and achieve a higher level of national health security. These include: improving access to medical care services; reforming and restructuring of the hospital sector; developing eHealth; improving quality control of medical activities; optimizing drug policy; improving dental health; promoting a long-term state policy in terms of human resources; promoting prevention programmes and improving early detection of diseases; improving total health financing and maximizing use of funds under the EU operational programmes.

The Concept Note also made an analysis of factors supporting health reform and threats related to its implementation (Table 9) and set out the main directions, priority actions and guidelines for achieving the objectives.

Table 9. Factors supporting health reform and threats related to its implementation

Supporting factors	Threats
Society's predominant expectation of reform	Maximalist expectations for quick positive results in a short time (months to years)
Health problems reported by all political parties – governing and opposition	No consensus among political parties on how to solve the problems
Presence of a majority in the National Assembly supporting government reforms	Possible attempts to use populism for short-term political dividends by opposition parties
Declared desire for reform both by patients and by health professionals	Possible negative reactions of both patients and health professionals in changing the status quo limiting their current benefits
Economic crisis that puts the need for more efficient spending on health	Limited financial resources for the support of the reform

Source: Ministry of Health 2010 (*95*).

Challenge 15. Ensuring access to care and reducing financial burden

Compulsory health insurance exists but one in eight is uncovered. According to the Health Insurance Act all Bulgarian citizens, permanent residents, refugees and those with humanitarian status or granted asylum are compulsorily insured with the NHIF. However, a significant share of up to 12% of the population is de facto uninsured, mainly unemployed individuals and those who choose not to contribute (*65*). Uninsured individuals belong to the most vulnerable groups. Intensive care for uninsured individuals and maternity services for uninsured women are covered through dedicated transfers of the Ministry of Health. Pensioners and children who are studying are insured by the state.

If lost, insurance coverage can be expensive to resume. People lose their insurance coverage if they have failed to pay more than three monthly contributions in the previous 36 months. To restore their insurance rights, individuals need to settle all contributions for the last 60 months.

The state guaranteed package of health services includes NCD prevention. According to the National Framework Agreement, the guaranteed package includes: primary and specialized outpatient medical care including general medicine, specialized and highly specialized care, diagnostic tests, hospital care, ambulatory clinical procedures, clinical pathways and complex ambulatory monitoring. Core individual services such as hypertension control, hepatitis B immunization and cervical cancer screening are included in the guaranteed health package.

Access remains a challenge in rural areas. Between 20% and 40% of the population experience restrictions on access to health services, 37.6% when purchasing prescribed medications and 30.6% when conducting medical diagnostic tests. Every fourth refrains from medical check-ups and/or tests when they are conducted outside the settlement where they live (25.8%), every sixth refrains from hospitalization (16%), and every seventh from various medical services due to long distance from home (13.7%). The place of residence seems to play a role also on preventive check-up attendance: city dwellers (67.5%) undergo preventive check-ups every year, while those living in the countryside and rural areas – mainly once every two years (23.4%) and once every three or more years (17.2%). Around 58.8% of older people undergo the mandatory annual preventive check-ups and the most common reasons for not attending were the lack of information (30.3%) and difficulties in reaching a GP (27.6%) (*97*). Incentives to GPs to work in underserved areas are the sole incentive to cope with inequalities of access.

Waiting times are low. A patient can see a GP within 24 hours and get an appointment for a specialist between one and three days. The legislation ensures a consultation with a specialist in less than 30 days. However, some small villages are visited by a doctor once a week. In 2017, to improve access in rural areas, the Ministry of Health provided additional funds to 64 hospitals located in hard-to-reach and remote areas. The funds were to provide services outside the scope of the NHIF such as long-term care for patients with cardiovascular, neurological and pulmonary diseases.

Out-of-pocket payments have increased over time, mostly driven by medicines, due to low public expenditure. Out-of-pocket payments accounted for 46.5% of all health expenditure in 2017, three times higher than the EU average of 15.3%. In 2015, the public share of the total expenditure on health was only 51.1% (one of the lowest in the EU), representing 4.2% of the GDP (*98*). This proportion could lead to around 12% of catastrophic health expenditure (*99*).

Bulgarians spend 5.4% of a household annual budget on health: pharmaceutical products (68%), outpatient services (15%) and hospital care (9%) (*100,101*). The household budget survey annually conducted by the National Statistical Institute does not provide disaggregated data by socioeconomic status or other relevant variables from an equity perspective.

Informal payments are high. Between 9.7% and 12.6% of outpatient services and between 18.3% and 31.8% of inpatient services users reported having done informal payments. Combining the burden of out-of-pocket payments and informal payments makes inability to pay especially pronounced and concerning among those with poor health status and chronic diseases and those on low household incomes who may remain excluded by the health system (*102,103*).

5. Innovations and good practices

5.1 Hospital performance benchmarking

Hospitals and healthcare facilities have invested in infrastructures to support health information systems to improve management and quality of care. These health information systems include electronic medical records and daily hospital management reports. These implementations have also been triggered by the monthly information reporting required by the NHIF. However, the information collected for funding and reimbursement purposes is not used to establish a comparative efficiency and quality effectiveness yardstick.

A national initiative called Best Hospitals (*90*) and sponsored by the Bulgarian Hospital Association sets forward national and regional hospital benchmarking. The initiative ranks and awards annually top performers in different dimensions such as patient and professional satisfaction, hospital management and quality accreditation. This initiative illustrates how the continuing investment in electronic health records and hospital information systems can provide new mechanisms to health authorities for strengthening quality and efficiency. Furthermore, the secondary use of health data for management and planning could contribute to set up pay-for-performance schemes through the National Framework Agreement.

5.2 International benchmarking for stroke

Since 2015, Bulgaria has been involved in international stroke care quality improvement initiatives. A growing number of stroke physicians have joined a comprehensive programme that aims at improving stroke care in Europe, ESO-EAST "Enhancing and Accelerating Stroke Treatment" (*104*). The programme is promoted by the European Stroke Organisation and consists of various activities, the main asset of which is participation in an international stroke registry, the RES-Q registry (*105*). RES-Q is designed to act as a tool for monitoring the stroke care pathway in the acute phase of all stroke types. The chosen performance measures allow for standardized comparison of stroke care quality (*106*) and include indicators for the following areas: stroke severity, stroke unit care, diagnosis, acute stroke recanalization therapy and timeliness of interventions for ischaemic stroke, surgery for Intracerebral haemorrhage, prevention of complications, secondary prevention therapies, early assessment for rehabilitation within the first 72 hours after hospital admission and destination at discharge. A growing number of hospitals admitting stroke patients have joined the registry during the last two years: 29 of the 133 hospitals that in 2018 had admitted stroke patients are currently using RES-Q and have enrolled 10 740 patients; the list of participating hospitals is in Table 10.

Table 10. Bulgarian hospitals participating in the RES-Q Registry (June 2019)

Supporting factors	Hospital name – unit	Hospital name – unit
First MHAT Sofia	MHAT Sveti Panteleimon	UMHAT Medika Ruse – neurology
MHAT Dobrich	MHAT Targovishte	UMHAT Pleven
MHAT Dr Atanas Dafovski	MHAT Trakia	UMHAT Plovdiv
MHAT Dr Nikola Vasiliev	MRHAT Dr Stefan Cherkezov – ICU	UMHAT St George
MHAT Dr Tota Venkova	MRHAT Dr Stefan Cherkezov – neurology	UMHAT St Naum Sofia
MHAT Haskovo	Tokuda Hospital Sofia – neurology	University Hospital Panagyurishte
MHAT Silistra	UHAT St Anna, Sofia – neurology	University Hospital Pulmed
MHAT Puls	UMHATEM N.I. Pirigov	University Hospital Sofiamed
MHAT Shumen	UMHAT Heart and Brain	University Hospital St Marina – neurology with ICU and stroke unit
MHAT National Cardiology Hospital	UMHAT "Angel Kanchev" University of Ruse	

ICU: intensive care unit; MHAT: Multiprofile Hospital for Active Treatment; MRHAT: Multiprofile Regional Hospital for Active Treatment; UHAT: University Hospital for Active Treatment; UMHAT: University Multiprofile Hospital for Active Treatment; UMHATEM: University Multiprofile Hospital for Active Treatment and Emergency Medicine

The data of each centre are immediately available for comparison and benchmarking. Performance indicators of stroke care obtained from the RES-Q registry have been presented during conferences, as posters and/or oral communications but not published yet as a whole. Multiple educational activities are associated with participation in the RES-Q registry, the most articulated is the Angel Initiatives (*107*), a multifaceted stroke care implementation intervention that has involved since 2016, includes 43 hospitals and is sponsored by Boehringer Ingelheim.

6. Policy recommendations

Bulgaria demonstrates progressive commitment to the global NCDs agenda. The National Programme for the Prevention of Chronic Noncommunicable Diseases 2014–2020 provides an overarching framework based on interagency work. The state guaranteed package of health services includes NCD prevention and the public health capacity for health needs assessment, health planning, monitoring, evaluation and surveillance relevant to NCDs are available.

There are systematic efforts to address inequalities in access, particularly in rural areas and for specific population groups such as children and adolescents and older adults. A mandatory social health insurance aims at providing universal access to a package of services across the country, including free access to medicine for cancer and diabetes.

Health system reforms in the last years have sought to strengthen the overall governance towards efficiency and transparency by reinforcing the gatekeeping function of GPs, implementing medical standards, improving the payment mechanisms to health providers (e.g. clinical pathways), enhancing managerial autonomy in the use of resources, incentivizing health professionals towards specializing and relocating to underserved areas, strengthening mechanisms for using the Positive Drug List to contain the cost of medicines, developing some "high-tech/high-cost" complex interventions, improving emergency medical care, establishing a national health system based on individual health records and establishing health assessment for technologies. Bulgaria also has good practices to build upon. Some highlights include achievements in health information and international benchmarking.

The result is a myriad of institutional initiatives set out to increase public spending efficiency, accountability and transparency disconnected from public health objectives to reduce premature mortality, particularly due to cancer and CVD, while tackling the root causes of behavioural risks, particularly those linked to smoking and alcohol abuse.

There is much to be done. Bulgaria is facing a demographic crisis, due in part to premature mortality. The probability of dying young from NCDs is one in three for men, twice as high for men as for women. Tobacco use and harmful use of alcohol are relatively high with trends worsening: two in three male drinkers do so harmfully. It seems to be easy to start smoking and drinking (almost the worst rates for young people in Europe) but hard to stop (underdeveloped tobacco cessation services for example) and regulatory measures are not being fully enforced. Overconsumption of salt, high rates of overweight/obesity and low rates of physical activity add to the challenges. Furthermore, regarding individual services, there is an opportunity for better prevention of NCDs and their complications. While there is a strong focus on periodic preventive medical examinations, these are resource-intensive, not reaching the whole population, and do not follow an evidence-based approach to reduce the burden of CVD in society. Cancer screening, early detection and palliative care are areas that warrant attention.

Hospitals consume most resources since incentivized to admit patients but discharge early. Patients, in turn, are interested to be admitted to hospitals where medicines are fully covered and bypass GPs. In some cases, like unemployed people, emergency medical services are the only possibility to access care. GPs are encouraged to single practice with an unlimited number of individuals in their lists and, given the caps, to refer them to outpatient specialist services rather than to focus on quality health outcomes for a given population/list. As a result, Bulgaria had the highest hospital admission rates for heart failure, diabetes mellitus and asthma among all EU countries in 2015. There are regional imbalances of medical professionals who are mostly concentrated in urban areas. Geographical and social differentials in access to services, low public investment for health, high out-of-pocket payments for medicines and low quality of care are imperatives that require concerted political direction and actions.

In order to overcome these challenges, strategic directions and policy recommendations are proposed below to accelerate progress in tackling NCDs. These are to be understood as pointers towards a comprehensive and aligned approach to further strengthening health systems for improving the response to NCDs.

Strategic direction 1. Converging health policy and planning efforts around prevention of priority NCDs and chronic care, reinforcing an intersectoral approach and securing adequate funding

Strengthened governance ensures coherent policy frameworks and sustainable intersectoral action for NCDs, connecting the national, regional and local levels. Such coherence provides an envelope to ensure adequate levels of resources with a focus on equity in public health actions. Universal health coverage requires access to needed health services for all population groups as well as financial protection against catastrophic and impoverishing health expenditures.

The policy recommendations are as follows.

- Align objectives of health reforms to ensuring higher health status and better quality of life, building on existing progress and challenges.
- Take a gender transformative approach that aims at acknowledging, challenging and changing some of the social norms and roles deeply rooted in society and in the health system that may have a negative impact on the health of men.
- Enforce regulatory measures for tobacco and alcohol control and scale up implementation of effective interventions for NCD prevention such as HPV vaccination.
- Engage relevant sectors in a whole-of-government approach to preventing NCDs to enable comprehensive approaches to salt and obesity reduction, for example.
- Promote and facilitate dialogue with non-state actors, patient associations, providers and professionals to bring their strengths into planning, service redesign, management and evaluation.
- Upskill public health competences to monitor and manage NCDs, particularly to expand their role in prevention and stratification of the population while strengthening the coordination with the RHIs and health insurance fund branches.
- Increase the efficiency and level of public spending to tackle inequalities created by out-of-pocket payments.
- Review and extend health benefits for those temporary unemployed, uninsured, with low income and working in the informal sector.

Strategic direction 2. Increasing the response capacity of PHC and communities towards maximizing health promotion and disease prevention opportunities, and supporting patient-centred care

A model of care that promotes multiprofile, integrated PHC that proactively manages community health and well-being has shown to be cost-effective to respond to the prevention and control of NCDs. This model of care requires a fit-for-purpose health workforce to deliver people-centred interventions and services based on evidence, the alignment of incentives to providers, access to quality medicines and adequate information solutions for seamless care and self-management.

The policy recommendations are as follows.

- Strengthen continued education for health professionals aligned with the national priorities and participated by professional associations and scientific societies.

- Scale up services and strengthen referral pathways for NCD prevention, for example to support tobacco cessation and reduce harmful alcohol use, and counsel on healthy behaviours, such as healthy eating and increased physical activity.
- Engage and support patients with chronic diseases in self-management.
- Empower patients and the public to make healthy and informed choices through the development of health-supporting environments and settings, access to personal e-health records and health literacy initiatives.
- Implement NCD risk factor surveillance systems, including regular population-level surveys of risk factors, to enable identification of issues, tracking trends and measuring impact of policies.
- Improve the organization and quality of cancer screening programmes to achieve better outcomes.
- Reinforce the GP gatekeeper role to limit direct access to specialized and hospital care.
- Review and address the geographical and by-specialty distribution of health providers, expanding the number and scope of practice of nurses.
- Roll out and consolidate the e-prescription system recently introduced including conducting qualitative reviews.
- Harmonize the positive list of medicine and the CPGs while promoting the use of generics and reviewing the reimbursement scheme for retailing in pharmacies.

Strategic direction 3. Optimizing the functional clinical networks and reference centres for selected NCD conditions

Organization of hospital services requires a nuanced approach given the drivers for and against centralization. The resultant model should be in line with the patient's needs and the type of service being provided. Adequately regionalized specialist services provide efficient and timely care for acute conditions. Conditions such as cancer, ACS and stroke require multidisciplinary, highly specialized and technology-dependent care while more common chronic diseases, such as diabetes, respiratory diseases and ischaemic heart disease, allow for innovative decentralized approaches to population health and ways of working.

The policy recommendations are as follows.

- Reprofile hospitals and specialized care to exploit the underutilized facilities' capacity for new services such as nursing care and palliative care among others.
- Redesign access to specialized and inpatient care in terms of volume of service, health professional workload, technology available, travel distance and availability of health providers across regions, exploring the use of telemedicine.
- Improve transitions of patients including data exchange among providers, case management, discharge and follow-up procedures.
- Improve collaboration and interaction between outpatient and inpatient services and emergency care.
- Align financial incentives to discourage over-hospitalization, and promote quality, performance and coordination, including the revision of caps on referrals, lack of maximum number of patients in the GP's list, encouraging multipractices, recruitment of nurses and other allied professionals.
- Enhance coordination between the health and social sectors, particularly relevant to older people and social cases.

Strategic direction 4. Developing a multi-level quality governance system based on NCD outcomes

Policy-makers must create enabling conditions for the system's actors to translate policies and standards into action while working towards improving health outcomes and well-being. Health providers need well-aligned quality mechanisms and processes that promote accountability for managing complexity, solving problems and thinking creatively when addressing the unique circumstances of individual patients with NCDs, and managers need to ensure performance management of facilities. The alignment of these mechanisms and processes fuel learning and overall quality of care improvement by way of feeding back to inform future public health priorities.

The policy recommendations are as follows.

- Establish learning loops based on performance and health outcomes to improve coordination and feedback.
- Use available data for supporting quality improvements in clinical practice, performance management of facilities, benchmarking among providers and, overall, accountability and quality assurance systems for population health.
- Strengthen, sustain and exploit existing disease registries, and establish other relevant disease registries, for enhancing population health management.
- Strengthen and modulate clinical pathways to become tools for improving quality of care rather than only payment tools.
- Expand medical standards towards processes and results and the establishment of a more articulated accreditation system rather than licensing.
- Develop new and increase the dissemination and uptake of clinical practice guidance, particularly those for NCDs, involving professional associations and incorporating them into the e-health records.
- Increase efforts to promote informed decisions by patients regarding treatment options, confidentiality, reports of patient experience and outcomes to inform policies.

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Annex 1. Data sources and methods

The principal sources of data on demographic and health-related indicators for this report were from the European Health for All databases accessed through the European Health Information Gateway (*1*) and the Global Health Observatory data repository (*2*). The indicators selected for analysis are based on expert recommendations and practical considerations of the available evidence.

Estimates and projections from data reported annually by the 53 Member States of the WHO European Region were used. Country subgroups defined in the European Health for All database were applied to distinguish regional trends where relevant:

- EU-15: the 15 Member States in the European Union before May 2004: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom;
- EU-13: the 13 Member States that joined the European Union since May 2004: Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia;
- the Commonwealth of Independent States until 2006: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan; and
- South-eastern Europe Health Network (SEEHN) members: Albania, Bosnia and Herzegovina, Bulgaria, Israel, Montenegro, North Macedonia, the Republic of Moldova, Romania, Serbia.

The countries in the WHO European Region that are not in these groups are: Andorra, Iceland, Monaco, Norway, San Marino, Switzerland and Turkey.

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Annex 2. Criteria for scoring tobacco-, alcohol- and nutrition-related interventions

Table A2.1. Criteria for scoring coverage of population-based interventions on tobacco control

Coverage	Limited	Moderate	Extensive
Range of antismoking interventions (WHO Framework Convention on Tobacco Control)	**Prevalence among adults > 30%**	**Prevalence among adults 18–20%**	**Prevalence among adults < 18%**
Raise tobacco taxes	Tax is < 25% of retail price	Tax is 25–75% of retail price	Tax is > 75% of retail price
Smoke-free environments	100% smoke-free environment enforced only in schools and hospitals	100% smoke-free environment enforced in hospitals, schools, universities, public transport and workplaces	100% smoke-free environment enforced in all public places, including hospitality sector
Warnings of dangers of tobacco and smoking	Warning labels required on tobacco products (size not specified)	Warning labels required on all tobacco products covering ≥ 30% (front and back)	Warning labels required to cover > 50% (front and back), with graphics (standardized packaging)
Bans on advertising, promotion and sponsorship	No ban on national television, radio or in print	Ban on direct and indirect advertising and promotion	Ban on all advertisement and promotion, including points of sale, with effective enforcement
Quit lines and nicotine replacement therapy*	No quit lines; Government-funded cessation services, with nicotine replacement therapy allowed if paid in full by the individual	Quit lines; Government-funded cessation services available (possibly with payment by individuals); nicotine replacement therapy available if paid in full by the individual	Free-of-charge quit line, with cessation services and nicotine replacement therapy available and affordable (covered at least partially)

*Additional criteria not included in the Global action plan for the prevention and control of noncommunicable diseases 2013–2020 (*1*).
Source: WHO Regional Office for Europe (*2*).

Table A2.2. Criteria for scoring coverage of population-based interventions to prevent harmful use of alcohol

Coverage	Limited	Moderate	Extensive
Raise taxes on alcohol	Alcohol taxes follow price index	Alcohol taxes follow price index, with special taxes on products attractive to young people	Alcohol taxes follow price index and are related to alcohol content, including special taxes on products attractive to young people
Restrictions or bans on advertising and promotion	Regulatory framework regulates the content and volume of alcohol marketing	Regulatory framework regulates the content and volume of alcohol marketing, including direct and indirect marketing and sponsorship	Full ban on alcohol marketing of any kind
Restrictions on availability of alcohol in retail sector	Regulatory framework exists on serving alcohol in government and educational institutions	Regulatory framework exists on serving alcohol in government institutions, and serving alcohol is banned in educational institutions	All governmental and educational institutions must be alcohol free
Minimum purchase age regulation and enforcement*	Minimum purchase age of 18 years for all alcohol products	Minimum purchase age of 18 years for all alcohol products and effective enforcement measures are in place	Minimum purchase age of 18 years for all alcohol products, effective enforcement measures are in place with loss of licence for illegally selling alcohol to people aged < 18 years
Allowed blood alcohol content for driving	Maximum of 0.5 g/L	Maximum of 0.5 g/L and zero for novice and professional drivers	Maximum of 0.2 g/L and zero for novice and professional drivers
Multisector policy development*	Multisector national strategy on alcohol policy	Multisector national strategy and a coordinating council on alcohol policy	Multisector national strategy, a coordinating council on alcohol policy and an adequately resourced nongovernmental sector, free of potential conflict of interest with public health

* Additional criteria not included in the Global action plan for the prevention and control of noncommunicable diseases 2013–2020 (*1*).
Source: WHO Regional Office for Europe (*2*).

Table A2.3. Criteria for scoring coverage of population-based interventions on diet and nutrition

Coverage	Limited	Moderate	Extensive
Interventions to improve diet and physical activity	Prevalence of overweight and obesity in children and adults (pre-obesity and obesity) is ≥ 30%	Prevalence of overweight and obesity in children and adults (pre-obesity and obesity) is 20–30%	Prevalence of overweight and obesity in children and adults (pre-obesity and obesity) is< 20%
Reduce salt intake and salt content in foods	≤ 10% reduction in salt intake has been registered since the mid-2000s	Salt intake has been reduced by ≥ 10% since the mid-2000s	Salt intake has been reduced by > 10% since the mid-2000s
Virtually eliminate *trans*-fatty acids from the diet	No evidence that *trans*-fats have been significantly reduced in the diet	*Trans*-fats have been reduced in some food categories and in certain industries but not overall	*Trans*-fats are virtually eliminated from the food chain through government legislation and/or self-regulation
Reduce free sugar** intake*	Reduction of the intake of free sugars** is mentioned in policy documents, but no action has been taken	Reduction of the intake of free sugars** by 5% is mentioned in policy documents and partially achieved in certain food categories	Reduction of the intake of free sugars** by 5% is monitored, with a focus on sugar-sweetened beverages
Increase intake of fruit and vegetables*	The aim to increase consumption in fruit and vegetables is mentioned, but no monitoring data have been collected	The aim to increase consumption of fruit and vegetables is in line with the WHO/FAO recommendations of ≥ 400 g/day, and some initiatives exist	The aim to increase consumption of fruit and vegetables is in line with the WHO/FAO recommendations of ≥ 400 g/day, with population initiatives in place and incentives to increase availability, affordability and accessibility
Reduce marketing pressure of food and non-alcoholic beverages to children*	Marketing of foods and beverages to children is noted as a problem, but has not been translated into specific action in government-led initiatives	WHO recommendations on marketing have been acknowledged and steps have been taken in self-regulatory approach to reduce marketing pressure on children	WHO recommendations on marketing and a framework for implementation are followed consistently, including a mechanism for monitoring
Promote awareness about diet and activity	No workforce development for nutrition and physical activity; nutrition and physical activity are not priorities in primary care	Some workforce has been developed for nutrition and physical activity; nutrition and physical activity are considered priorities in primary care	Workforce has been developed for nutrition and physical activity; nutrition and physical activity are priorities in primary care

FAO: Food and Agriculture Organization of the United Nations.
*Additional criteria not included in the Global action plan for the prevention and control of noncommunicable diseases 2013–2020 (*1*).
**Free sugars are monosaccharides (such as glucose, fructose) and disaccharides (such as sucrose).
Source: WHO Regional Office for Europe (*2*).

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Annex 3. Criteria for scoring coverage of individual services

NCD	Limited	Moderate	Extensive
CVD and diabetes			
Risk stratification in PHC	10-year CVD risk documented in fewer than 30% of records of patients aged >40 years with at least one main CVD risk factor. Specific risk factors not routinely documented.	10-year CVD risk documented in 30–60% of records of patients aged >40 years with at least one main CVD risk factor. Incomplete risk factor documentation or not using systematic method.	10-year CVD risk routinely documented in more than 60% of records of patients aged >40 years with at least one main CVD risk factor. Systematic method of calculation with routine documentation of specific risk factors.
Effective detection and management of hypertension	Fewer than 30% of estimated cases with high blood pressure identified in PHC, evidence-based generic antihypertensive drugs infrequently prescribed, no efforts to address patient adherence.	30–60% of estimated cases with high blood pressure identified in PHC, evidence-based antihypertensive drugs often (25–75%) prescribed, some efforts to increase patient adherence but not systematic.	More than 60% of estimated cases with high blood pressure identified in PHC, evidence-based generic antihypertensive drugs routinely (>75%) prescribed; government-funded systematic efforts to increase adherence.
Effective primary prevention in high-risk groups	Prescribers unaware of indications for primary prophylaxis. Under 10% of patients with very high (>30%) 10-year CVD risk identified and prescribed multidrug regimens (antihypertensive, acetylsalicylic acid and statin) for primary prophylaxis. Acetylsalicylic acid prescribed indiscriminately to all hypertensive patients.	Prescribers aware of indications for primary prevention with multidrug regimen. Low coverage (10–25%) of very high-risk patients with primary prophylaxis or appropriate drug regimens prescribed but very low patient adherence. Acetylsalicylic acid prescribed indiscriminately to all hypertensive patients.	Routine prescription of multidrug regimens, including statins, for patients at very high CVD risk. Coverage of at-risk patients exceeds 25%. Evidence of good long-term patient adherence. Acetylsalicylic acid not prescribed to hypertensive patients with low or medium CVD risk.
Effective secondary prevention after AMI including acetylsalicylic acid	Fewer than 25% of patients after AMI receive acetylsalicylic acid, beta-blockers and statins.	25–75% of patients after AMI receive acetylsalicylic acid, beta-blockers and statins.	More than 75% of patients after AMI receive acetylsalicylic acid, beta-blockers and statins.
Rapid response and secondary care after AMI and stroke[a]	Fewer than 25% of those with AMI or stroke receive diagnosis and care within six hours of first symptoms.	25–50% of those with AMI or stroke receive diagnosis and care within six hours of first symptoms.	More than 50% of those with AMI or stroke receive diagnosis and care within six hours of first symptoms.

	Limited	Moderate	Extensive
Diabetes			
Effective detection and general follow-up[a]	Fewer than 75% of PHC practices establish and maintain a register of all patients aged ≥17 years with diabetes. <25% detection/registration rate, based on estimated prevalence of type 2 diabetes in adult population. Not using evidence-based, systematic method to select asymptomatic patients for screening.	25–75% of PHC practices establish and maintain a register of all patients aged ≥17 years with diabetes. 25–50% detection/registration rate, based on estimated prevalence of type 2 diabetes in adult population. Using evidence-based, systematic method to select asymptomatic patients for screening, but limited coverage.	More than 75% of PHC practices establish and maintain a register of all patients aged ≥17 years with diabetes. More than 50% detection/registration rate based on estimated prevalence of type 2 diabetes in adult population. Using evidence-based, systematic method to select asymptomatic patients for screening with high coverage.
Patient education on nutrition and physical activity and glucose management	Fewer than 25% of those diagnosed with type 2 diabetes made at least three PHC visits in past year. Fewer than 25% of registered people with diabetes receive organized dietary counselling. PHC gives no counselling about physical activity. Fewer than 25% of registered people with diabetes had glycosylated haemoglobin measurement in past 12 months.	25–75% of those diagnosed with type 2 diabetes made at least three PHC visits in past year. 25–75% of registered people with diabetes receive organized dietary counselling. PHC routinely offers counselling on physical activity. 25–75% of registered people with diabetes had glycosylated haemoglobin measurement in past 12 months.	More than 75% of those diagnosed with type 2 diabetes made at least three PHC visits in past year. More than 75% of registered people with diabetes receive organized dietary counselling. PHC routinely offers counselling and options for physical activity through partnerships. More than 75% of registered people with diabetes had glycosylated haemoglobin measurement in past 12 months.
Hypertension management among diabetes patients	Fewer than 25% of registered people with diabetes with hypertension have achieved a blood pressure <140/90 mmHg; ACE inhibitors not routinely prescribed as first-line antihypertensive.	25–75% of registered people with diabetes with hypertension have achieved a blood pressure <140/90 mmHg; ACE inhibitors routinely prescribed as first-line antihypertensive.	More than 75% of registered people with diabetes with hypertension have achieved a blood pressure <140/90 mmHg; ACE inhibitors routinely prescribed as first-line antihypertensive.
Preventing complications	Fewer than 25% of registered people with diabetes had foot and eye examinations (fundoscopy) and urine protein test in past 12 months.	Fewer than 25% of registered people with diabetes had foot and eye examinations (fundoscopy) and urine protein test in past 12 months.	More than 75% of registered people with diabetes had foot and eye examinations (fundoscopy) and urine protein test in past 12 months.
Cervical, breast and colorectal cancer screening			
Screening coverage	Screening is not population-based[b] (coverage is usually unknown).	The screening programme is largely population based[b] but coverage remains below 50% of the eligible population.	The screening programme is population based[b] and coverage is above 50% of the eligible population.

NCD	Limited	Moderate	Extensive
National screening guidelines	Absence of clear guidelines (or various contradicting guidelines) regarding age to screen, frequency of screening and test to use. OR Use of tests that are not evidence based.[c]	Clear guidelines regarding age to screen, frequency of screening and test to use AND (Guidelines partly not evidence based (for age group,[d] frequency of screening[e] and tests used[c]) OR Gaps in the way guidelines are applied.)	Clear guidelines regarding age to screen, frequency of screening and test to use. AND Guidelines are evidence based (for age group,[d] frequency of screening[e] and tests used[c]). AND Guidelines are applied throughout the whole country.
Screening algorithm to follow up those screened positive	Unclear or inadequate algorithm regarding steps to follow after a positive screening test. OR Major gaps in the way algorithms are applied throughout the whole country. OR Follow-up for those screened positive is not free of charge.	Clear and adequate algorithm regarding steps to follow after a positive screening test. AND (Gaps in the way algorithms are applied throughout the whole country. OR Follow-up for those screened positive is not free of charge.)	Clear and adequate algorithm regarding steps to follow after a positive screening test. AND Algorithms are applied throughout the whole country. AND Follow-up for those screened positive is free of charge.
Monitoring and evaluation	Absence of monitoring and evaluation system. OR Monitoring and evaluation system largely inadequate. OR Data are largely missing.	A monitoring and evaluation system is in place but there are gaps in its design or in the data collection.	An adequate monitoring and evaluation system is in place.

[a] Additional criteria not included in the global action plan for the prevention and control of noncommunicable diseases 2013–2020 (1).
[b] Population based: i.e. all people in a defined age group are identified from population registries and are invited individually by means of a letter/e-mail/text message on a regular basis (every 2, 3 or 5 years according to national guidelines).
[c] The following tests are evidence based: HPV test, Pap test, visual inspection of the cervix, mammography, faecal occult blood test, sigmoidoscopy and colonoscopy.
[d] Evidence-based age groups are: 50–69 years for mammography screening (not younger), 30–49 years for cervical screening (but can be extended to 25–65 years) and > 50 years for colorectal cancer screening (should not begin before the age of 50).
[e] Frequency of screening should not be more than every 2 years for mammography and the faecal occult blood test.

References

1. Global action plan for the prevention and control of noncommunicable diseases 2013–2020. Geneva: World Health Organization; 2013 (https://apps.who.int/iris/handle/10665/94384, accessed 4 February 2020).
2. Better noncommunicable disease outcomes: challenges and opportunities for health systems. Assessment guide. Copenhagen: WHO Regional Office for Europe; 2014 (http://www.euro.who.int/en/health-topics/Health-systems/health-systems-response-to-ncds/publications/2014/better-noncommunicable-disease-outcomes-challenges-and-opportunities-for-health-systems.-country-assessment-guide-2014, accessed 4 February 2020).

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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World Health Organization
Regional Office for Europe
UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark
Tel: +45 45 33 70 00 Fax: +45 45 33 70 01
Email: eurocontact@who.int
Website: www.euro.who.int