National Center of Public Health and Analyses

ANALYTICAL REPORT ON THE ACTIVITIES RELATED TO THE HEALTH CARE OF THE POPULATION IN RESPONSE TO THE COVID-19 PANDEMIC FOR THE PERIOD 01 MARCH 2020 – 31 MAY 2021

June, 2021

ANALYTICIAL REPORT ON THE ACTIVITIES RELATED TO THE HEALTH CARE OF THE POPULATION IN RESPONSE TO THE COVID-19 PANDEMIC FOR THE PERIOD 01 MARCH 2020 – 31 MAY 2021

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The Report is prepared in accordance with the Order № RD-01-381/28.05.2021 of the Minister of Health by a working group of experts of the National Centre of Public Health and Analyses:

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This report is dedicated to all the medical and non-medical experts from various departments and institutions who have made tremendous efforts to tackle the enormous challenge of COVID-19.

The authors are grateful to all the institutions that responded to the call for data needed to prepare the tables and graphs in this report.

It is our common hope that the findings and conclusions in the report will contribute to a more effective response by our society as a whole to any future similar threats.

Introduction

In the beginning of 2020, the world was struck by an unexpected and unmanageable disaster that overthrew many perceptions about the security of the world's health systems and the modern European's sense of safety and security. The coronavirus pandemic originated in China and spread rapidly to the centre of Europe, and subsequently to all continents, affecting nearly all countries for a brief moment in time.

In Bulgaria, the pandemic was declared on 13 March 2020 along with the first cases of infection in Bansko and Pamporovo, and—by order of the Minister of Health—a state of emergency and a number of accompanying measures to combat the infection were declared. A National Coronavirus Task Force (NCTF) was set up to take on the challenge of coordinating and managing the pandemic crisis.

It has been more than a year since the official announcement of the COVID-19 pandemic in Bulgaria and the creation of the NCTF. During this period, Bulgaria has suffered significant losses, mainly in human fatalities and economic consequences. The mortality figures, which show that in terms of overall mortality Bulgaria is one of the leading countries in Europe and even in the world, are cause for serious concern. This report attempts to investigate the causes of this high overall mortality rate, which, together with the death toll from COVID-19, has put the entire health system to the test and given rise to serious concern about how the pandemic is being managed in the country and what conclusions can be drawn for the future.

The report is prepared on the basis of information gathered from the Regional Health Inspectorates (RHI), the Ministry of Health (MoH), the National Social Security Institute (NSSI), the National Health Insurance Fund (NHIF), the National Statistical Institute (NSI), the National Centre for Infectious and Parasitic Diseases (NCIPD) and the Bulgarian Medical Association (BMA). Letters were sent to all of these institutions with specific questions about the data in their databases and related to COVID-19. The analysis of the information received is presented by category according to the different sectors of the health system in Bulgaria.

Part 1

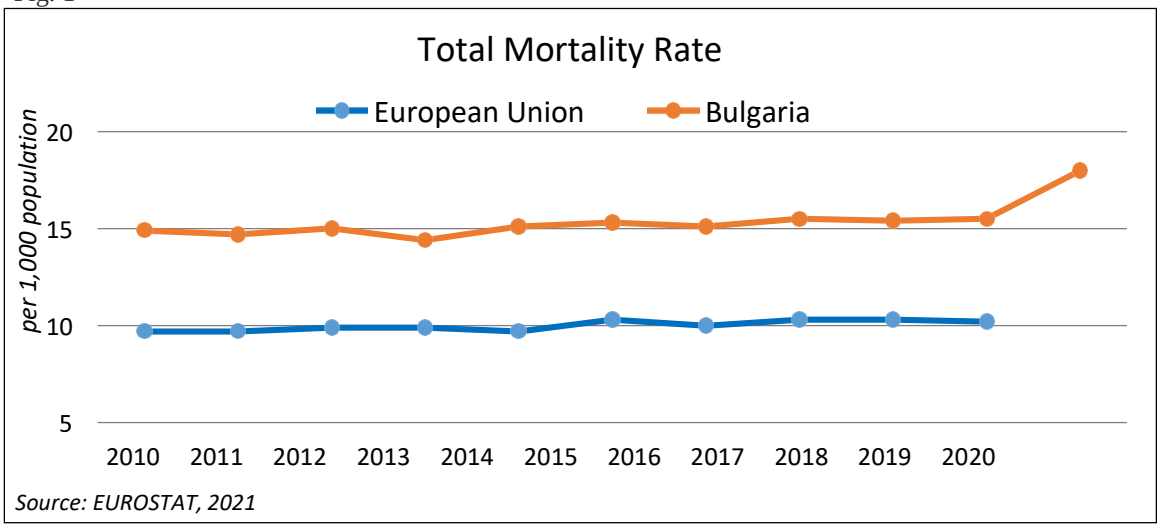
Analysis of the mortality

Mortality in Bulgaria during the period from 1 March 2020 to 30 May 2021

In the field of statistics, mortalities are fundamental demographic events that are recorded at the time of their occurrence, but are collected in periodic clusters covering a calendar year for the purposes of the current demographic statistics. During statistical processing, the aggregates of all demographic events, including mortalities, are distributed by current address. During statistical processing, the aggregates of all demographic events, including mortalities, are distributed by current address. In a mortality study, the totality of deaths is observed and used to calculate the indicators characterising mortality. A key indicator is the mortality rate, which shows the number of persons who died per 1,000 persons in the average annual population. It is calculated in per mille as the ratio of the number of deaths in a year to the average annual population in that year. The source of the data for the calculation of the number of deaths is the Unified System for Civil Registration and Administrative Service of the Population (USCRASP).

One of the reasons for the steady and objective trend towards a deteriorating demographic situation in Bulgaria observed in recent years is the high mortality rate. National data show that in 2020 the mortality rate (18.0‰) is the highest ever reached in history since 1945 (*latest available data — publication 'Population – NSI'*). Based on data from Eurostat, the mortality rate in 2019 for the EU as a whole is 10.2‰, and for Bulgaria 15.5‰. The overall mortality rate in Bulgaria was the highest among the EU Member States in every year during the period 2010 to 2019. (Figure 1)

Fig. 1



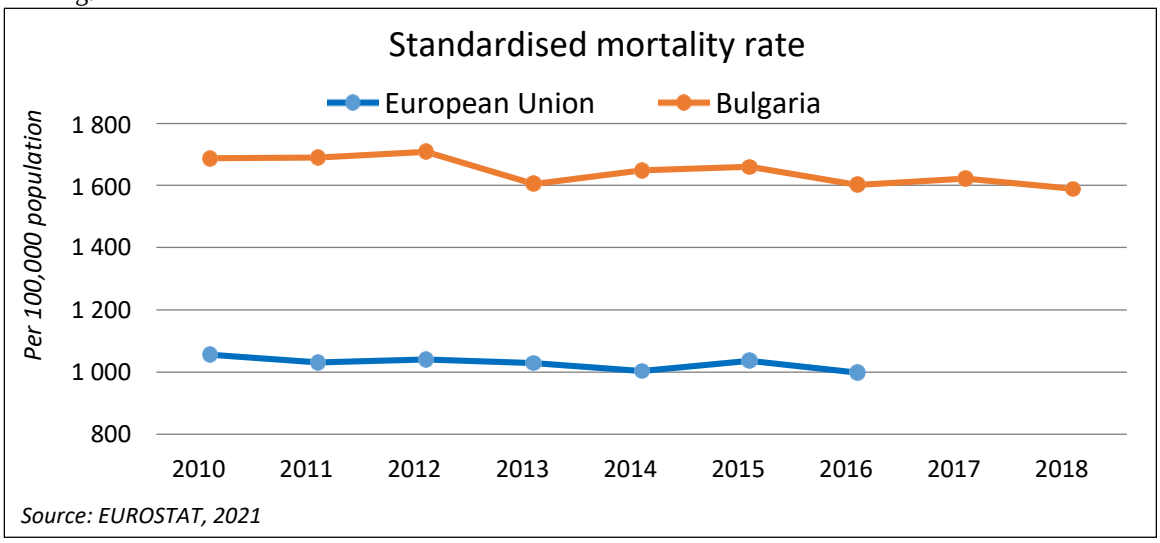
The most frequently used indicators are the crude mortality rates per 1,000 population. They give an indication of the process itself, but when using this general indicator, one must always consider the fact that it is strongly (and increasingly over time) influenced by the age structure of the population. Data from Eurostat shows that the relative share of the population aged 65 or above on average in the EU is 20% of the total population. For Bulgaria, this indicator amounts to 21.6%, with Italy (23.2%), Finland (22.3%) and Portugal (22.1%) ranking ahead.

In determining mortality rates in comparative terms between countries, it is necessary to compare standardised mortality rates using the so-called 'standard population'. A standard population is a

population with a 'standard structure' that remains constant when comparing mortality rates across different populations. This method of calculating mortality—through the use of standardised rates—allows for comparisons (e.g., between countries) to be made in a relatively cleaner form, eliminating the influence of age distribution, which is often cited as a major cause of high mortality.

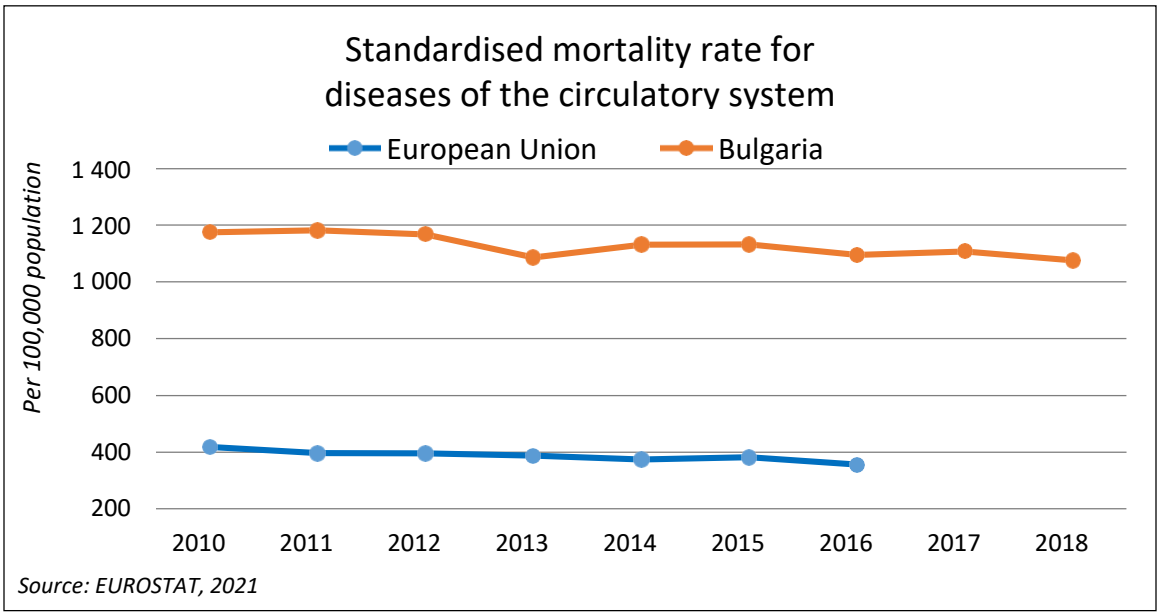
The standardised mortality rates show the same ranking of Bulgaria in relation to the overall EU indicator as well as in relation to the other countries. On average, the standardised mortality rate for the EU is 997.6‰ (2016), while for Bulgaria it stands at 1601.9‰ (2016) and 1588.6‰ (2018), thus defining it as the country with the highest standardised mortality rate among the Member States for each year of the period examined. (Figure 2)

Fig. 2



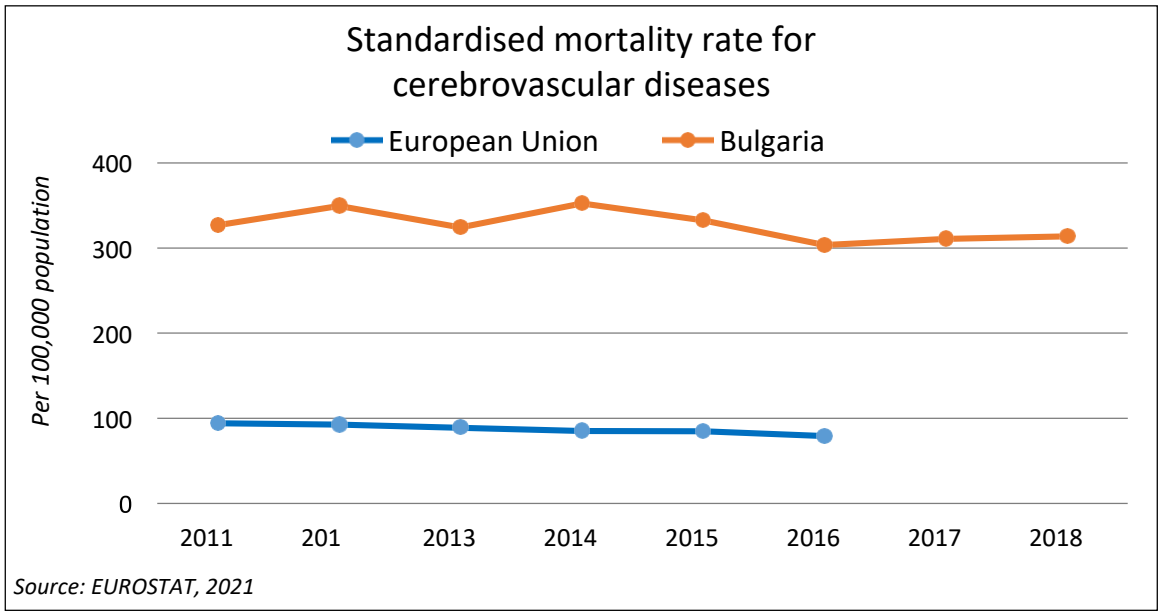
Besides total mortality, Bulgaria also ranks first in the EU in other *standardised mortality rates*. In 2016, the standardised mortality rate for diseases of the circulatory system averaged 356‰ for EU countries, while for Bulgaria it was three times higher – 1095‰, and in 2018 it amounted to 1076‰. (Figure 3)

Fig. 3



Bulgaria also ranks first among EU countries in the *standardised mortality rate* for cerebrovascular diseases. In 2016, this indicator for the EU amounted to 79‰, while for Bulgaria it is more than three times higher – 304‰ in 2016 and 314‰ in 2018. (Figure 4)

Fig. 4

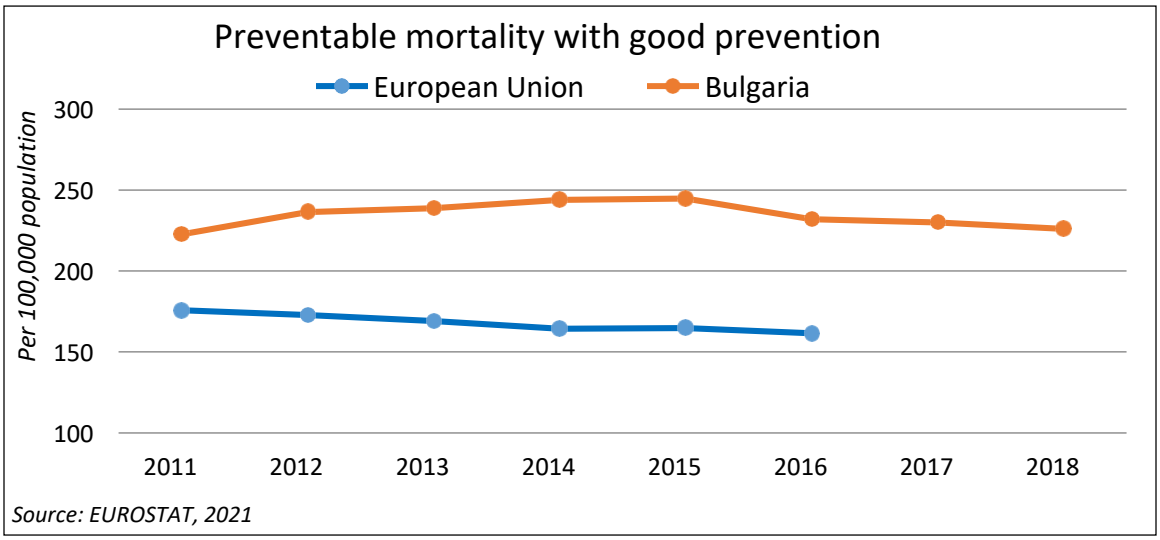


The number of avoidable or preventable fatalities is identified as a marker for the overall evaluation of health systems and the outcomes of their activities and public health interventions.

The concept of *preventable death* is based on the idea that certain fatalities would not have occurred at a given time point if more effective health and medical interventions had existed, as well as the possibility that they could have been avoided through public health interventions targeting behavioural and lifestyle factors, socioeconomic status and environmental factors.

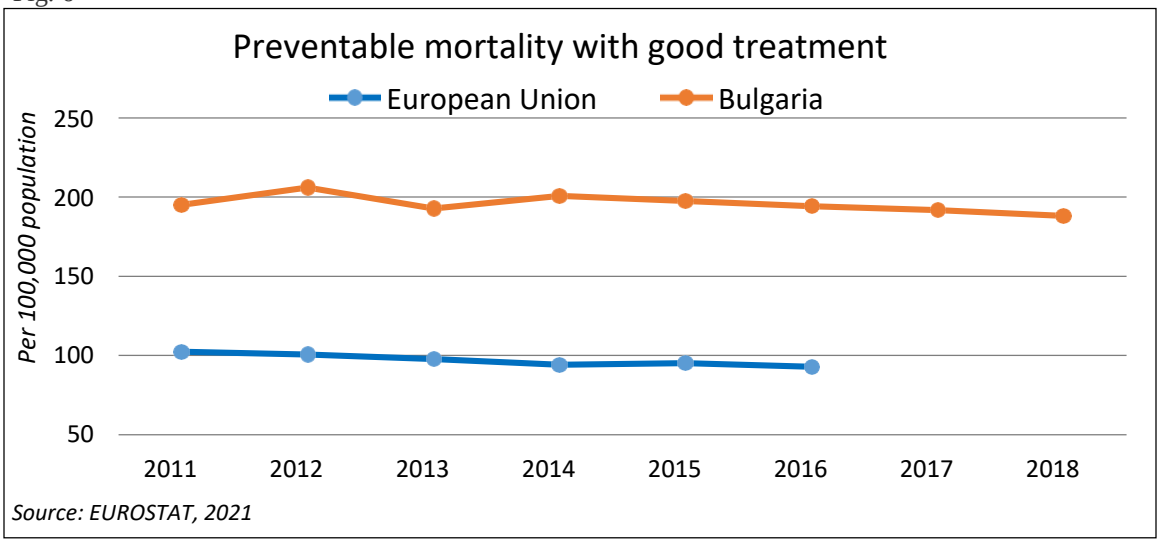
According to data from Eurostat, the EU average for *preventable mortality with good prevention* is 162‰ (2016), while for Bulgaria – 232‰ (2016) and 226‰ (2018). Seven EU countries have a higher figure than Bulgaria. (Figure 5)

Fig. 5



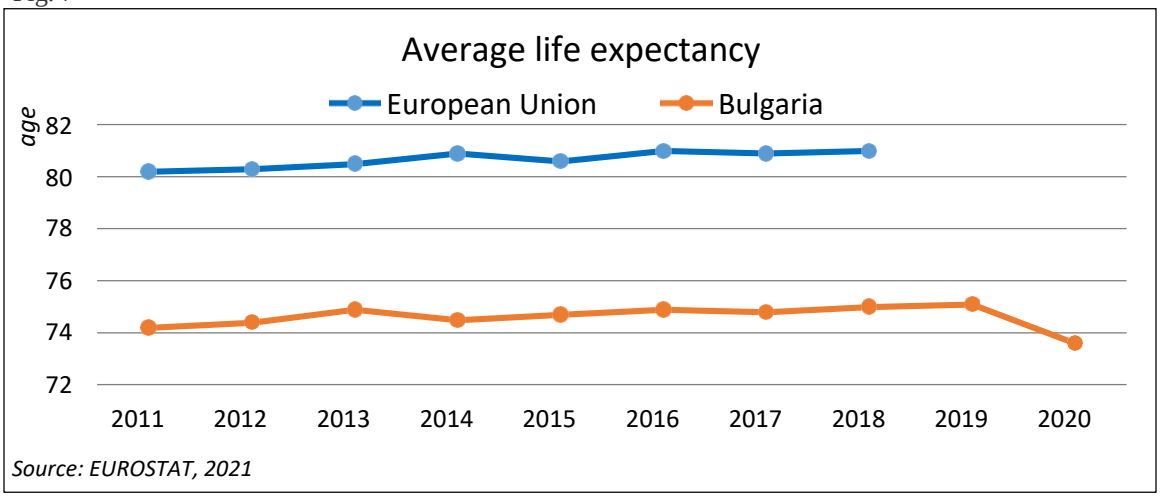
Bulgaria ranks worse in terms of the indicator for *preventable mortality with good treatment*. The average indicator for EU countries is 93‰ (2016), while for Bulgaria it is twice as high – 194‰ (2016) and 188‰ (2018). Only two EU countries have a higher value of this indicator than Bulgaria. (Figure 6)

Fig. 6



The expected life expectancy in Bulgaria has maintained its upward trend in the period from 2014 to 2019, but in 2020 it decreased by 1.5 years, which is a sharp decline against the backdrop of the slow and smooth evolution of this indicator over the years. According to data from Eurostat, in 2018 this indicator in Bulgaria is 6 years lower than in the EU. Bulgaria has ranked last in the EU in life expectancy over the last 7 years. (Figure 7)

Fig. 7



Source: EUROSTAT, 2021

Even more worrying is that years lived in good health are below the EU average, which alongside the ageing population with multiple chronic diseases will prove a challenge for the health system.

These figures show that there is a need to formulate policies aimed at reducing mortality in Bulgaria based on an analysis of the main determinants of health and the capacities of the health system.

Mortality in Bulgaria during the period from 1 March 2020 to 30 May 2021

In analysing the mortality in Bulgaria for this period, the following particularities should be noted:

- The period under consideration from 1 March 2020 to 30 May 2021 is a time period that exceeds the scope of a calendar year.
- During 2020, the COVID-19 spread covers 10 months – from 1 March until the end of December.
- In 2021, available data for 5 months were used – from January until 30 May.
- There are no reported SARS-CoV-2 cases in Bulgaria in 2019.
- The data used for mortality by week are for periods, respectively: 31.12.2018–29.12.2019 (for 2019), 30.12.2019–03.01.2021 (for 2020) and 04.01.2021– 30.05.2021 (for 2021).
- The sources of the data used for the analysis are the National Statistical Institute, Eurostat, the European Centre for the Prevention and Control of Infectious Diseases and the Unified Information Portal.

During the period examined from 01.03.2020 to 31.05.2021, a total of 166,050 people died in the country. Their distribution by age group shows that the largest relative proportion of deaths was in the age group 80-89 years – 31%, followed by deaths in the age group 70-79 years – 29%, and in the age group 60-69 years – 18%. This makes a total of 78% of all deaths during the period examined in the age group 60-89 years.

For a more expanded comparative profile, the annual data by week for 2019 and 2020 and the 5-month data of 2021 were also used. In 2019, a total of 107,815 people died, of which 33% aged 80-89 years, 27% aged 70-79 years and 18% aged 60-69 years, or a total of 78% of all deaths during the year were in the age group 60-89 years.

The data for 2020 shows an increase in the number of deaths to 126,569, an increase of 18,754 or 17% compared to 2019, whilst maintaining the same age distribution – 31% were aged 80-89 years, 28% aged 70-79 years and 18% aged 60-69 years, or a total of 77% of all deaths during the year were persons in the age group 60-89 years.

The total number of deaths during the period 04.01.2021-30.05.2021 amounts to 59,892. The distribution by age groups shows the same proportions – 31% of the persons who died were aged 80-89 years, 30% aged 70-79 years and 18% aged 60-69 years, or a total of 79% of all deaths during the year were persons aged 60-89 years.

To track the rate of deaths over the observation period, intensity indicators—weekly mortality rates—were used. *The weekly total mortality rate (‰)* is calculated in per mille as the ratio of the number of persons who died during the respective week to the average annual population multiplied by 365 and divided by 7.

The mortality rates by week for the period from 01.03.2020 to 31.05.2021 show that the highest intensity of deaths occurs at two time-intervals, in two waves. The length of the periods was determined on the basis of mortality rates that are approximately equal at the entry and exit of the respective wave.

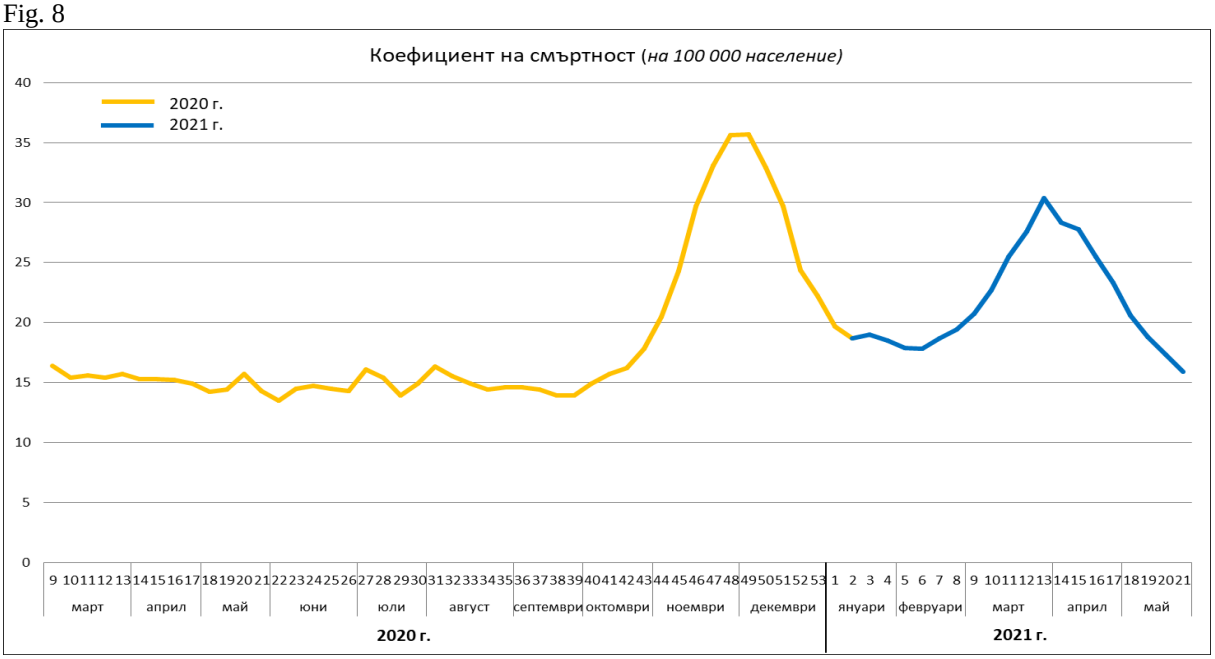
For the first time interval, these values are 18‰ (43rd week of 2020) at the onset of the wave and 20‰ (1st week of 2021) at the exit of the wave.

- *First wave* – covering 10 consecutive weeks (from the 44th to the 53rd week in 2020), when the peak mortality rates reach 36‰ in the 48th and 49th weeks.

For the second time interval, the values of the weekly mortality rates are respectively 19‰ (8th week of 2021) at entry into the wave and also 19‰ (19th week of 2021) upon exiting the wave.

- *Second wave* – covering 10 consecutive weeks (from the 9th to the 18th week in 2021), when the peak mortality rate reaches 30‰ in the 13th week. (Figure 8)

Fig. 8



Source: NSI

A comparison of the data for the two crisis intervals with highest mortality also shows that:

- during the period from the 44th to the 53rd week in 2020, 38,330 persons died, which is an increase of 19,545 or 104% compared to the same period of the previous year 2019;
- during the period from the 9th to the 18th week in 2021, 33,298 people died, which is an increase of 12,898 or 63% compared to the same period in 2020 and an increase of 12,234 or 58% compared to the same period in 2019.

A regional overview of mortalities

The breakdown of the number of deaths in the period 1.03.2020-30.05.2021 by districts shows that the largest districts in the country are at the top. The district with the highest number and relative share is the district Sofia-city – 24,023 deaths and 14% of the total number of deaths for the period, followed by Plovdiv – 15,341 deaths and 9% of the total number of deaths, Varna – 9,350 deaths and 6% of the total number of deaths, Burgas – 8,454 deaths and 5% of the total number of deaths, Stara Zagora – 7,863 deaths and 5% of the share, Pleven – 6,938 deaths and 4% of the share, Sofia-region – 6,572 deaths and 4% of the share, Blagoevgrad – 6,443 deaths and 4% of the share, Pazardzhik – 6,386 deaths and 4% of the share, and Veliko Tarnovo – 6,001 deaths and 4% of the share. These 10 districts accounted for 59% of the total number of mortalities in the period examined.

In 2019 and 2020, 58% of deaths were recorded in these 10 districts and 59% in the period 4.01.2021-30.05.2021.

The data for 2020 show an increase in the number of mortalities compared to the previous year, both nationally as well as for all districts.

The review of total mortality rates by district shows that they increase in 2020 compared to 2019 for all districts. The top two positions in both years (when ranked in descending order) are the districts of Vidin and Montana.

Comparing the data by district for the two time-intervals (two waves) in 2020 and 2021, when mortality is at the highest, shows the following:

- During the period **from the 44th to the 53rd week in 2020**, the district with the highest increase in the number of deaths compared to the same period of 2019 is Razgrad – with 134%, followed by Silistra – with 133%, Blagoevgrad – with 124%, and Ruse – with 122%;
- During the period **from the 9th to the 18th week in 2021**, the district with the largest increase in the number of deaths compared to the same period in 2020 is Sofia – with 81%, followed by Dobrich – with 78%, Pleven – with 74%, Montana – with 71%, and with the largest increase compared to the same period in 2019 is Shumen – with 82%, Kardzhali – with 70%, Smolyan – with 69%, and Silistra – with 68%.

Mortality from SARS-CoV-2 in Bulgaria during the period 1 March 2020 to 30 May 2021[1]

During the period under review, from 01.03.2020 to 31.05.2021, a total of 17,657 people died of SARS-CoV-2 in the country, accounting for 11% of the total number of deaths during the same period. Data by week for 2019 and 2020 and for the 5-month period from 02/01/2021 to 30/05/2021 were used for a more extended comparison.

Monitoring the data for the entire period under review shows that the marked increase in deaths from SARS-CoV-2 started from the 45th week of 2020 (the second week of November), when 353 persons died, and peaked in the 48th and 49th and 51st weeks, when the rates rose almost 3-fold. There were 929 deaths in week 48, 980 deaths in week 49 and 925 deaths in week 51. On the basis of these data, the first wave of the pandemic in the country is marked by high mortality (from the 45th to the 51st week of 2020). SARS-CoV-2 deaths in this time interval account for 17.9% of the total number of deaths from all causes in the same period.

After the 51st week of 2020 until the 9th week of 2021, there is a decrease in the number of deaths, with a weekly average of 367 for this period.

The second wave, which features a new rise in SARS-CoV-2 mortalities, is formed in the time interval from the 10th week of 2021, when the number of deaths was 641, until the 17th week (585 deaths). Peak levels are reached in weeks 13 and 14, with 857 and 844 deaths respectively. Deaths from SARS-CoV-2 during the second wave of the pandemic in the country, marked by high mortality, accounted for 21% of the total number of deaths from all causes during the same period (10th to 17th week of 2021).

During the period from the 44th to the 53rd week in 2020, 38,330 persons died—an increase of 19,545 or 104% compared to the same period in the previous year 2019. Of these 19,545 deaths, 6,560 or 34% were due to SARS-CoV-2.

During the period from the 9th to the 18th week in 2021, 33,298 people died—an increase of 12,898 or 63% compared to the same period in 2020, and an increase of 12,234 or 58% over the same period in 2019. Of these 12,566 deaths on average, 6,735 or 54% were due to SARS-CoV-2.

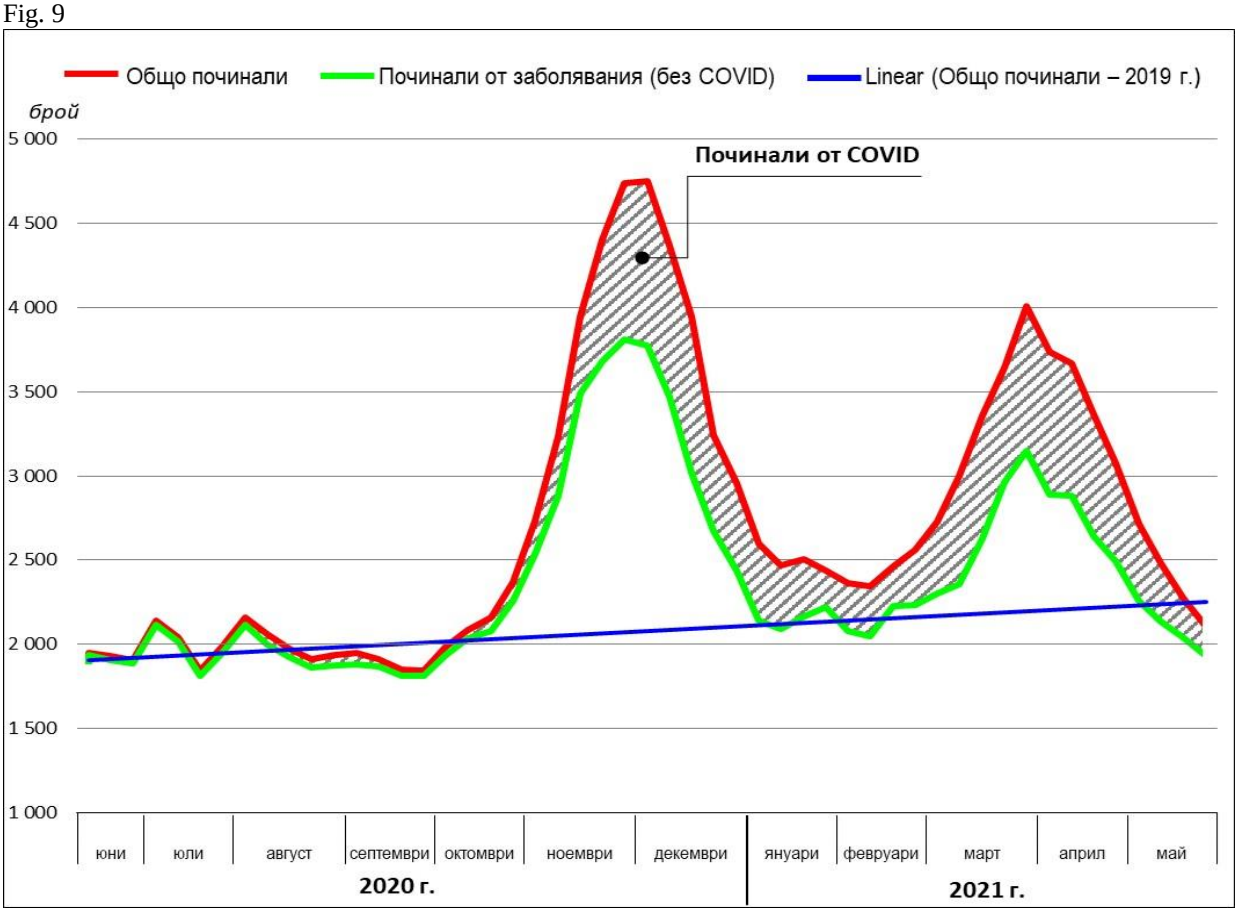
The breakdown of the data by week for the entire period under review from 01/03/2020 to

1 The data on the number of SARS-CoV-2 deaths in Bulgaria are from the Uniform Information Portal, the official national source of information related to the spread of the infection.

31/05/2021 shows that the relative proportion of SARS-CoV-2 deaths out of the total number of deaths from all causes since the beginning of the period is in the order of about 2% at the beginning of the period. From the end of October, it starts to increase and in the period of the first wave—November and December—this indicator reaches values of about 10 times higher – 20-23%.

Following some decline in the following months, during the second wave—March and April—the relative proportion of deaths from SARS-CoV-2 rose again to around 21-22% of the total number of deaths from all causes during the period under review. (Figure 9)

Fig. 9



Source: Unified Information Portal COVID-19

Mortality by causes – classes of diseases

The global emergence of a new SARS-CoV-2 infection in 2020 has necessitated the introduction of new codes for special purposes: COVID-19. Information related to morbidity, mortality, etc. with data for 2020 now includes cases under this code.

According to the National Statistics Institute's annual data on cause-specific mortalities in 2020, the total number of deaths was 124,735, of which 8,554, or 7%, were from SARS-CoV-2.

Compared to 2019, the absolute number of deaths increased by 16,652, of which 8,554 were due to COVID-19, with the remaining increase most notable in the classes 'Diseases of the circulatory system' – up by 5,954, and 'Diseases of the respiratory system' – up by 1,813.

The structure of causes of death by disease class shows that in 2020, compared to the previous year, the relative share of deaths from circulatory diseases decreased from 64.4% to 60.6%, and of deaths from neoplasms from 16.9% to 14.9%. The relative proportion of deaths from COVID-19 was 6.9%, ranking third in the structure of deaths by disease class, displacing respiratory diseases in fourth place. For the remaining disease classes, there are no significant differences in the figures in 2020 compared to the previous year 2019.

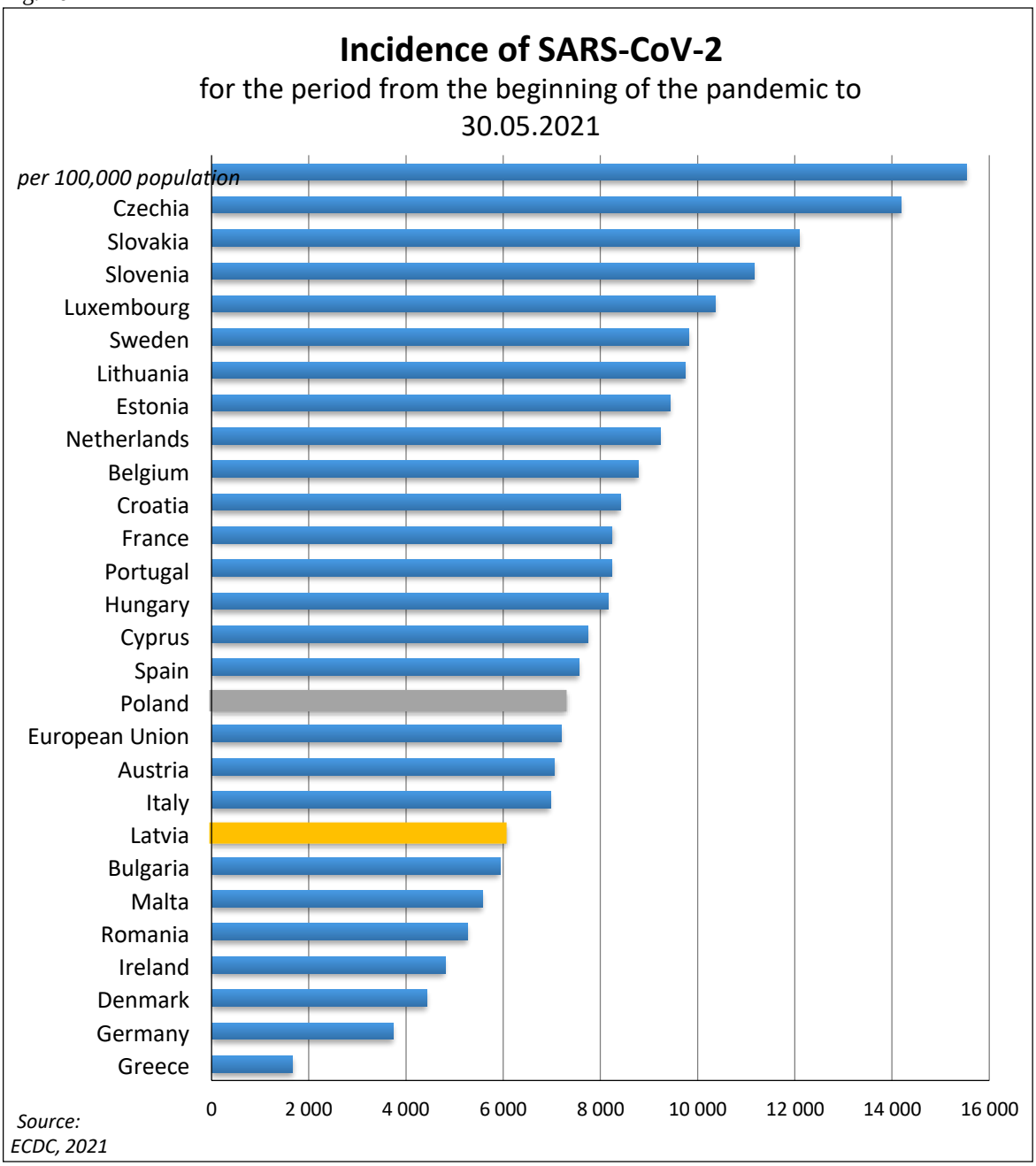
The mortality rates show that in 2020, compared to the previous year, the death rate from diseases of the circulatory system increased from 998.2‰ to 1090.1‰, and from diseases of the respiratory system from 60.1‰ to 86.6‰. The mortality rate from COVID-19 was 123.4‰ and no significant differences were observed for the other disease classes.

Morbidity and mortality on an international scale

The comparative analysis of SARS-CoV-2 morbidity and mortality in the European Union countries is based on data from the European Centre for Disease Prevention and Control. The period considered is from the beginning of the pandemic, which varies from country to country. The pandemic in Bulgaria, as well as in all other EU countries, started a process of formation of a complicating epidemic situation, associated with an increase in the number of patients and, consequently, with an increase in the mortality rate from SARS-CoV-2.

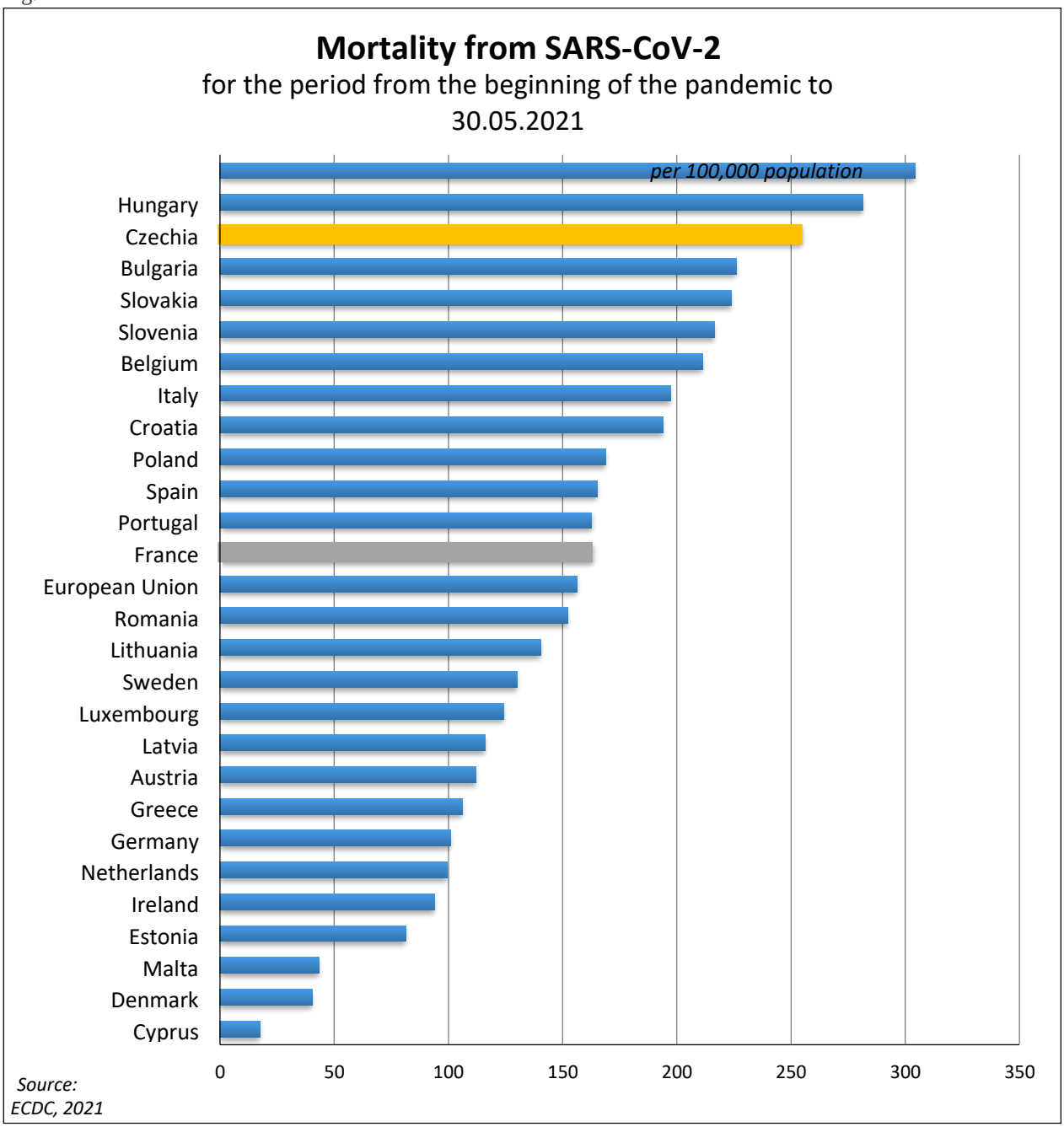
Incidence rates (number of cases per 100,000 population) show that, on average, 7,253 cases per 100,000 population occurred in the EU during the period considered. Eighteen Member States have a higher incidence than the EU average. The Czech Republic (15,534‰), Slovakia (14,184‰), Slovenia (12,095‰) have the highest incidence rates and Finland (1,672‰) the lowest. The incidence in Bulgaria is lower than the EU average at 6,016‰. (Figure 10)

Fig. 10



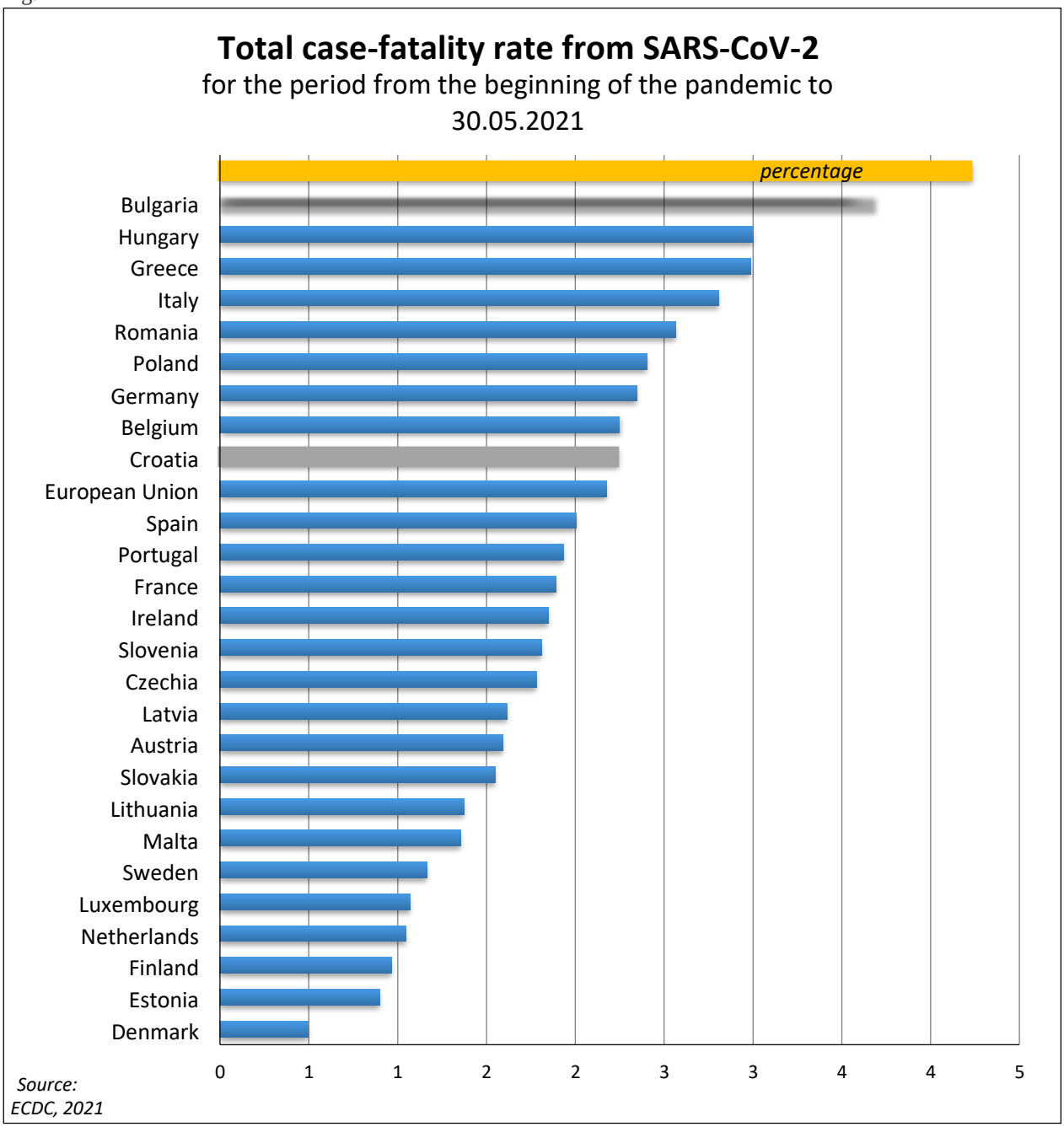
The data for individual countries shows that there is no clear-cut relationship between the incidence and mortality processes of SARS-CoV-2. For example, Hungary, which ranks 13th in the ranking of high to low incidence indicators, has the highest mortality (304‰). Bulgaria ranks 20th in terms of incidence but is 3rd in terms of mortality at 254‰. Of all EU countries, 12 have a higher SARS-CoV-2 mortality than the EU average, which stands at 162‰. (Figure 11)

Fig. 11



The calculated total lethality (the relative share of SARS-CoV-2 deaths of the total number of SARS-CoV-2 cases) shows that Bulgaria ranks first in this indicator with 4.2%, which is almost twice the EU average of 2.2%. Hungary also has a high overall lethality rate of 3.7%, Greece and Italy 3.0%, while Cyprus, Denmark, Estonia and Finland have the lowest rates of 1% and less than 1%. (Figure 12)

Fig. 12


Total case-fatality rate from SARS-CoV-2
for the period from the beginning of the pandemic to 30.05.2021
percentage
Bulgaria
Hungary
Greece
Italy
Romania
Poland
Germany
Belgium
Croatia
European Union
Spain
Portugal
France
Ireland
Slovenia
Czechia
Latvia
Austria
Slovakia
Lithuania
Malta
Sweden
Luxembourg
Netherlands
Finland
Estonia
Denmark
0
1
1
2
2
3
3
4
4
5
Source:
ECDC, 2021

Findings

The results of Bulgaria in terms of morbidity, mortality and case fatality rate from SARS-CoV-2 compared to other EU countries do not show a clear relationship of these indicators. In a descending order of indicators, Bulgaria ranks 21st in incidence, but third in mortality and first in total lethality.

The reasons for these ratios are complex—age structure of the population, incidence of serious chronic diseases, multiple socio-economic causes, behavioural factors, etc. The relationship with the state and functioning of the health system, its resources and adequate management in the process of emergence and development of SARS-CoV-2 infection is also indisputable. Particularly worrying is the fact that in Bulgaria the incidence of the infection is comparable to the data at the average European level, while the mortality rate is leading even on a global scale. This fact can be interpreted in three ways: either there is some unique factor at work in the country that is the cause of these high mortality rates, or the health system has done exceptionally poorly, or the registration of those infected and diseased is unreliable and incomplete.

Part 2

Analysis of the activities of emergency medical care centres

The challenge of COVID-19 has put the country's entire healthcare system, especially emergency and hospital care, to the test in 2020-2021. The pandemic situation was extraordinary, very dynamic, requiring rapid and adequate action. The COVID-19 pandemic has had a significant impact on the workload of emergency teams, and the large number of infected medical professionals has become a serious challenge in terms of ensuring sufficient teams.

Medical care for emergency cases is regulated in laws and regulations: Section III. Medical assistance in emergency conditions of the Law on Health; Ordinance No. 25 of 4 November 1999 on the provision of emergency medical assistance, which defines the scope, procedure and conditions for the provision of emergency medical assistance; Ordinance No. 3 of 6 October 2017 on the approval of the medical standard of emergency medicine, etc. The emergency medical care system includes 27 emergency medical care centres (EMCC) corresponding to the districts constituting the administrative division of the country, with 198 branches for emergency medical care (BEMC) affiliated to them, five outreach teams and the emergency departments in hospital care facilities. The EMCC's are secondary budget administrators of the Ministry of Health and their activities are fully financed by the State budget. The activities of the emergency departments are financed in accordance with Regulation No. 3 of 5 April 2019 on the medical activities outside the scope of compulsory health insurance. Emergency medical care centres and their affiliates are part of the structures of the health care system that are on the front line in the fight against the pandemic from COVID-19.

Completed activity under the "Emergency Medical Care" budget programme of the MoH

The aim of the "Emergency Medical Care" budget programme of the MoH[2] is to provide Bulgarian citizens and persons residing on the territory of the Republic of Bulgaria with timely, accessible and quality medical care for emergency conditions. The operational objectives are: 1) Ensuring equitable access of the population to emergency medical care in line with the best European practices and standards for quality and safety, and 2) improving the system for financing emergency care and ensuring its staffing and material-technical provision. Funding for the emergency medical care system in the Republic of Bulgaria is provided under the programme. The objectives of the programme are in line with the objectives and priorities set out in the Concept for Development of the Emergency Medical Care System 2014-2020 and the National Health Strategy 2020.

Programme activities:

- Development and promulgation of the *Regulations for the Amendment and Supplementation of the Regulations for the Establishment and Operation of an Emergency Medical Care Centre*. With the amendments and additions made, these Centres are given the possibility to validate their structure and staffing by functions and the possibility to

2 Report on the activities of the Ministry of Health under the budget programme "Emergency Medical Care", 2020.

implement flexible operational management.

- *Investment project BG16RFOP001-4.001-0001 "Support for the development of emergency medical care system"*, (with a total budget of BGN 163,897,815.62, of which BGN 163,502,132.68 from grant and BGN 395,682.94 from the beneficiary's own contribution, and the implementation term until 23.10.2021, financed under the Operational Programme "Regions in Growth" 2014-2020) for the renovation and modernisation of the building stock and equipment in the emergency system throughout the country—the emergency departments of 34 hospital care facilities, 27 Emergency Medical Care Centres (EMCC's) and their 170 affiliates (BEMC's) and 6 outreach teams. In 2020, the preparation of public procurement documents and the selection of contractors for the construction, renovation and reconstruction of the building stock of the emergency medical care centres were completed. At the end of 2020, the first contracts have been concluded with contractors for construction and installation works for the needs of outpatient emergency care structures in the South-Central Planning Region. Under the project, 226 new ambulances fully equipped with medical equipment, including 148 with standard drive and 78 with 4x4 drive, have been delivered to the emergency care centres in 2020. New ambulances are to be provided for all medical teams in the country. A contract has been signed with a contractor for the supply of non-diagnostic type medical equipment, which is in the process of being implemented.
- *Project BG05M9OP001-3.007-0001 "Improving conditions for the treatment of emergency conditions"* (with a total budget of BGN 7,000,000 and the deadline for implementation 30.09.2021) to improve the quality of emergency care through investment in human capital—the provision of theoretical and practical training to a minimum of 6,892 employees of the emergency medical care centres and the emergency departments at the National Centre for Training and Qualification in the Emergency Medical Care System. Since the start of the project trainings (November 2019) until 28.02.2020, 1,402 employees from all emergency care centres in the country have been successfully trained at the National Centre, of which 980 employees completed training in 2020 (doctors, health care specialists, paramedics and drivers) on topics directly related to the diagnosis and treatment of the most common emergency conditions. There has been a delay in the implementation of the project due to the restrictions placed on face-to-face training as part of the counter-epidemic measures against the spread of COVID-19. Following a public procurement procedure under the Public Procurement Act under subject 'Purchase of 170 computer configurations, with installed operating system, for the needs of newly established branches of the Emergency Medical Care Centres', a contract was concluded with the selected contractor. In the period reported, 100 unites of computer configurations were delivered for the needs of 17 EMCC's.
- In the process of preparation are the conditions for the implementation of a public procurement for the main activities under the *project BG16RFOP001-4.002-0001-C01 "Provision of air vehicles for emergency medical response" under Public Procurement "Regions in Growth" 2014-2020*.
- *The project BG05M9OP001-1.099-0001 "Support for workers in the health care system in conditions of the threat to public health from COVID-19"*, under which so far more than BGN 182.5 million have been paid for 121,643 additional salaries, continues to pay additional net monthly salaries of BGN 1,000 to all medical and non-medical professionals working on the frontline of the fight against COVID-19. The tax and social security contributions due to them are at the expense of the individuals and employers, as well as additional gross remunerations of BGN 610 to health mediators with the social security

contributions due to them at the expense of the employer. To this moment, additional remunerations have been paid to medical and non-medical professionals working on the frontline in the fight against COVID-19 throughout the country, and health mediators from all inpatient facilities where patients with COVID-19 are treated, mental health centres, comprehensive cancer centres, state psychiatric hospitals, emergency medical centres and their affiliates, regional health inspectorates, medical diagnostic laboratories, the National Centre for Infectious and Parasitic Diseases and municipalities. The project budget has been increased from BGN 60,000,000 to BGN 240,000,000 in order to be able to pay additional salaries to frontline workers in the fight against COVID-19.

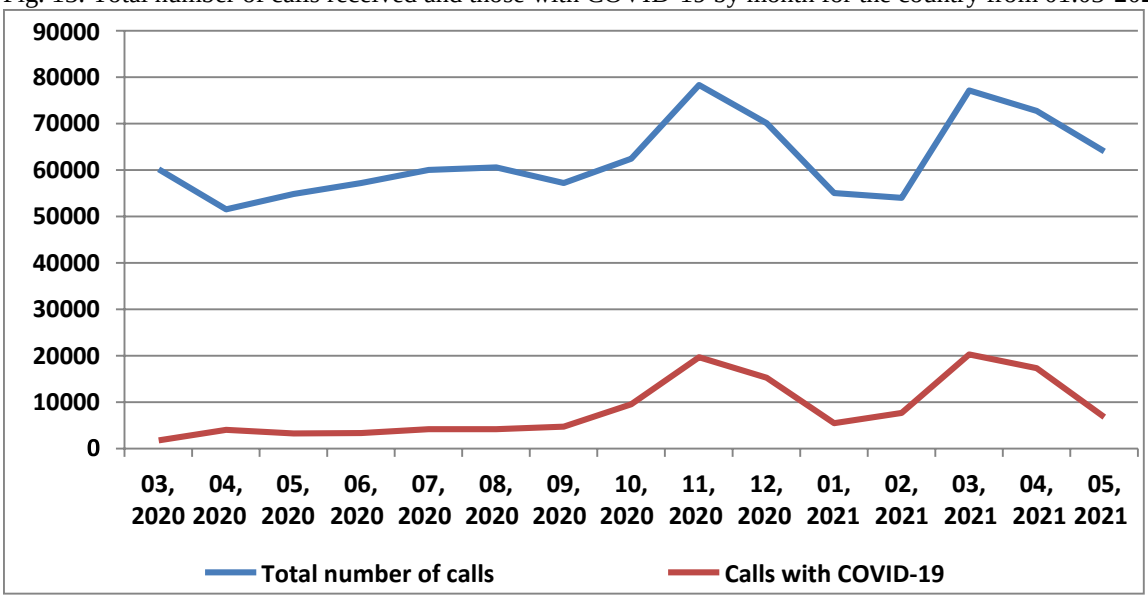
An updated overview of the latest developments in the pandemic was obtained during *regular videoconferences* with the 28 regional health inspectorates and the 27 emergency care centres in the country.

Received and executed calls

The total number of calls received in all EMCC's in the country for the period 01.03.2020-31.05.2021 is 936,517. Of these, 127,478 are COVID-19 related calls, representing 13.61% or one in seven COVID-19 related calls. Tracked by month, the total number of calls received and of those with COVID-19 corresponds to the peaks in the total number of infections in the country by month, i.e., the first wave of the pandemic (November-December 2020) and the second wave (March-April 2021). The highest number of calls were received in November 2020, March 2021, April 2021 and December 2020 (78,403; 77,188; 72,796; 70 164 calls, respectively).

The highest number of calls received for COVID-19 were in March 2021 (20,318), November 2020 (19,720), April 2021 (17,314), December 2020 (15,295) and October 2020 (9,571). (Figure 13)

Fig. 13. Total number of calls received and those with COVID-19 by month for the country from 01.03-2020 - 31.05.2021

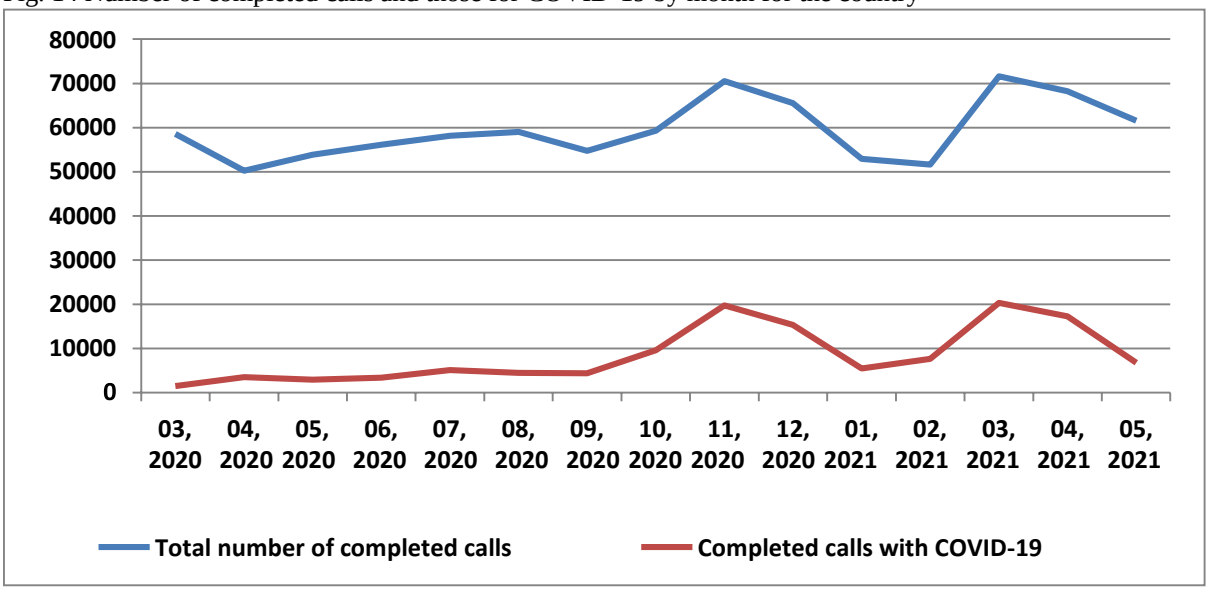


Source: MoH

The total number of completed calls is 891,789. Of these, 127,405 were completed calls related to

the disease COVID-19, representing 14.29%. The dynamics by month of the total number of calls and those for COVID-19 repeat that of the number of calls received in total and for COVID-19. The total number of completed calls is at its highest in March 2021 (71,625 calls), November 2020 (70,543 calls), April 2021 (68,220 calls) and December 2020 (65,515 calls). The completed calls for COVID-19 for the same months were respectively 20,318, 19,720, 17,314 and 15,295 calls. (Figure 14)

Fig. 14 Number of completed calls and those for COVID-19 by month for the country



Source: MoH

The proportion of completed calls to all incoming calls was 95.22%, and of completed calls for COVID-19 to incoming calls was 99.95%. The proportion of completed calls for COVID-19 is substantially higher than that of the total completed calls compared to the incoming calls—almost 100%. The number of calls received depends on the population of the district, morbidity, age structure of the population, etc. The number of completed calls alone is not indicative of the efficiency and quality of medical care provided, as it is influenced by many other factors such as population size and density, topography, morbidity, age structure of the population, etc. The highest number of total calls was received in the EMCC-Sofia (199,510 calls), Plovdiv (93,857 calls), Burgas (67,886 calls) and Varna (62,084 calls). The lowest number of calls was received in EMCC-Targovishte (5,691 calls). The highest relative share of completed calls was registered in EMCC-Ruse, Pazardzhik, Kyustendil, Kardzhali, Yambol and Vratsa (100%). In EMCC-Sofia, although high, this indicator is the lowest compared to the others – 82.50%. In the other EMCC's the indicator is over 97%.

The number of persons hospitalized by the EMCC and refusals for hospitalization[3]

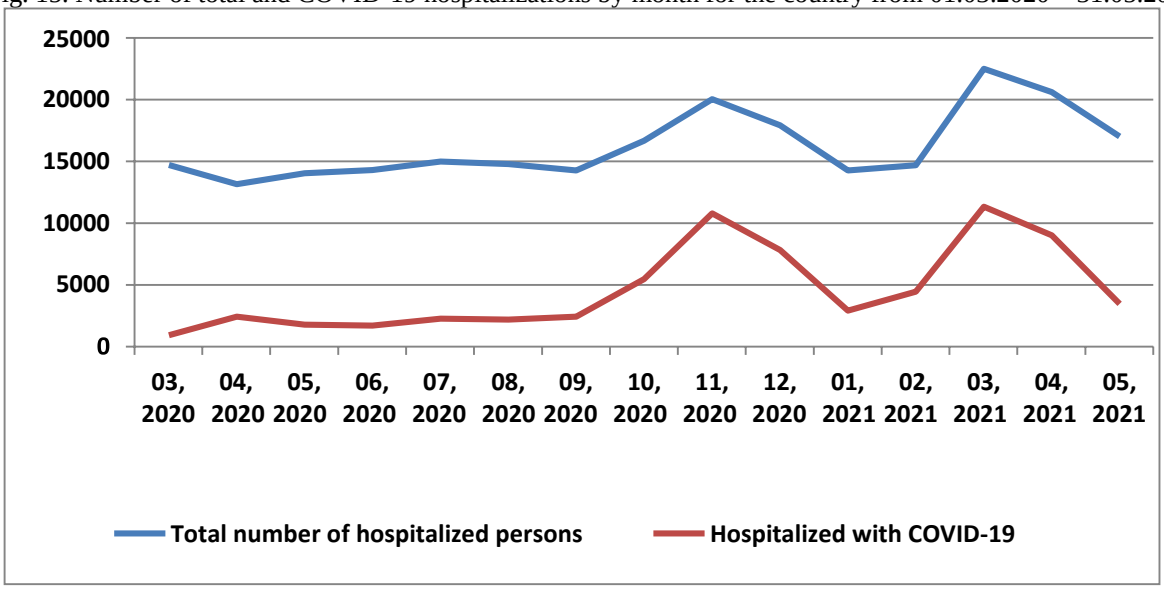
The total number of persons hospitalized by the EMCC in the country for the period under review was 243,885. Of these, 69,119 were hospitalized with COVID-19, which accounted for 28.34% of all hospitalizations, i.e. almost 1 in 3 hospitalizations was due to COVID-19. The number of

3 Based on the data provided by the staff of the EMCC, the information on hospitalized persons is incomplete due to the lack of feedback between the EMCC and the institution admitting them.
Indicators are calculated without data for Pazardzhik, Kyustendil and Kardzhali due to missing information.

persons hospitalized depends not only on the number, type and severity of the disease but also on the availability of hospital beds and their occupancy. This also determines to some extent the refusals of hospitalization received. From the available data on the total number of hospitalized persons (under the above-mentioned remark), it is found that the highest number of persons hospitalized by the EMCC's in total is reported in Sofia (40,276 persons), Plovdiv (31,367 persons), Burgas (22,065 persons) and Varna (19,356 persons), i.e. in the largest cities with high availability of hospital beds.

In terms of persons hospitalized by the EMCC's for COVID-19, the first place was taken by Sofia (23,005 persons), followed by Burgas and Plovdiv (5,433 and 4,951 persons respectively). The distribution of hospitalized persons in total by month corresponds to the monthly dynamics of the disease in the country—October-December 2020 and March-May 2021. The values range from 16,669 persons hospitalized in October 2020 to 22,493 persons in March 2021. The number of persons hospitalized with COVID-19 is highest in March 2021 (11,328 persons), November 2020 (10,784 persons) and April 2021 (9,021 persons). (Figure 15)

Fig. 15. Number of total and COVID-19 hospitalizations by month for the country from 01.03.2020 – 31.05.2021



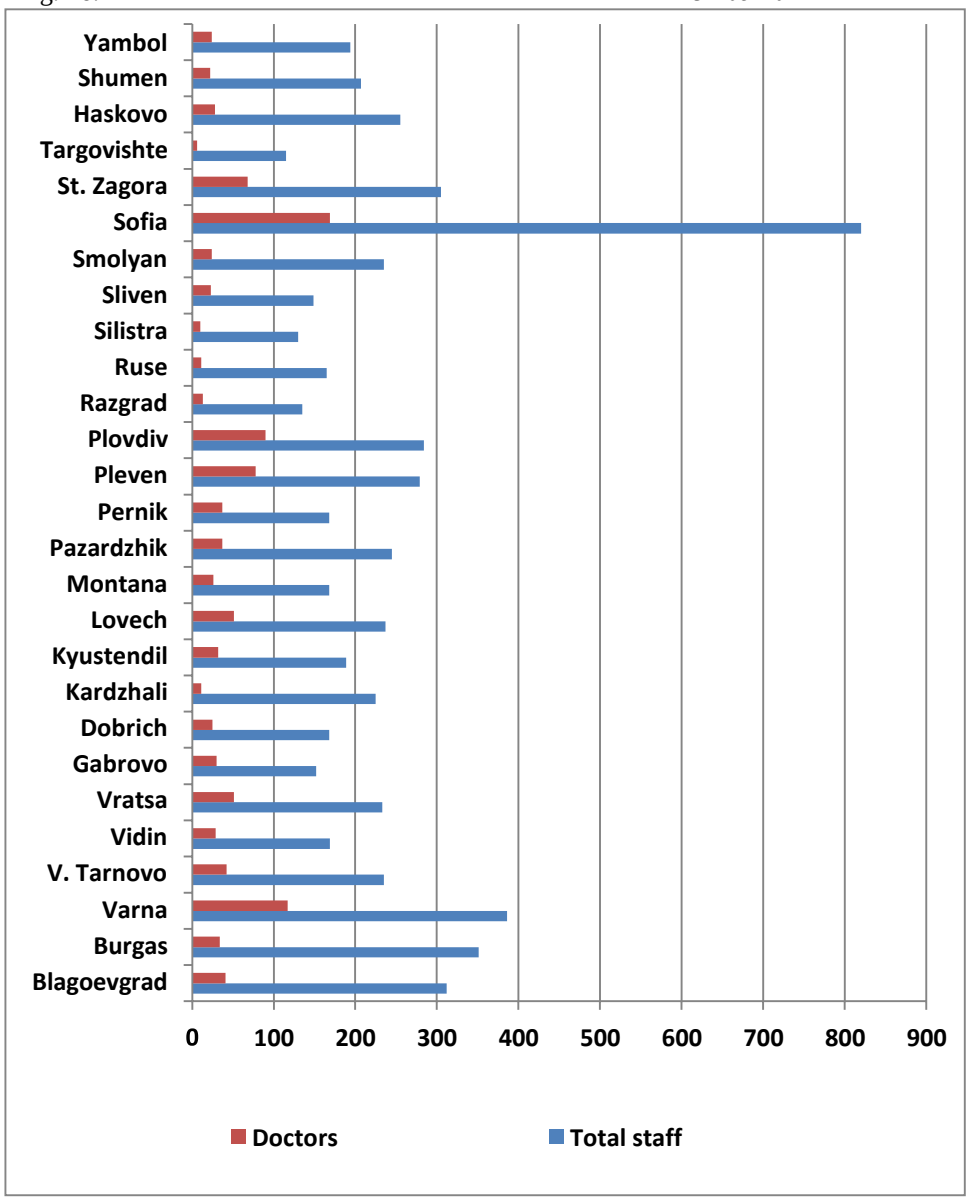
Source: MoH

The total number of refusals for hospitalizations was 20,576, with 14 EMCC's not providing information due to missing information. The number of refusals for hospitalization of persons with COVID-19 was 1,347, with missing information for 16 EMCC's. The proportion of COVID-19 refusals to all refusals is 6.55%.

Availability of medical staff

As of May 31, 2021, 6,511 employees work in the emergency medical care centres, of whom 1,129 are doctors and 5,382 other staff. Compared to March 2020, the total number of employees in the EMCC's (6,618) is reduced by 107 as a result of the reduction of other staff (from 5,489 to 5,382 respectively). In terms of total staff numbers, there are significant differences between centres, largely due to population size, the area served in the district, morbidity rates, etc. (Figure 16)

Fig. 16. Number of total staff and doctors in the EMCC's as of 31.05.2021



Source: MoH

The largest number of personnel as of 31.05.2021 is in the EMCC-Sofia (820, including 169 doctors), which is only logical, as it serves the population of two districts—Sofia-capital and Sofia-region. Next is EMCC-Varna with a total staff of 365, including 117 doctors; EMCC-Burgas with 350 total staff; Stara Zagora with 305 staff, Plovdiv with 284 staff and Pleven with 279. The smallest number of doctors is in EMCC-Targovishte with 6 doctors.

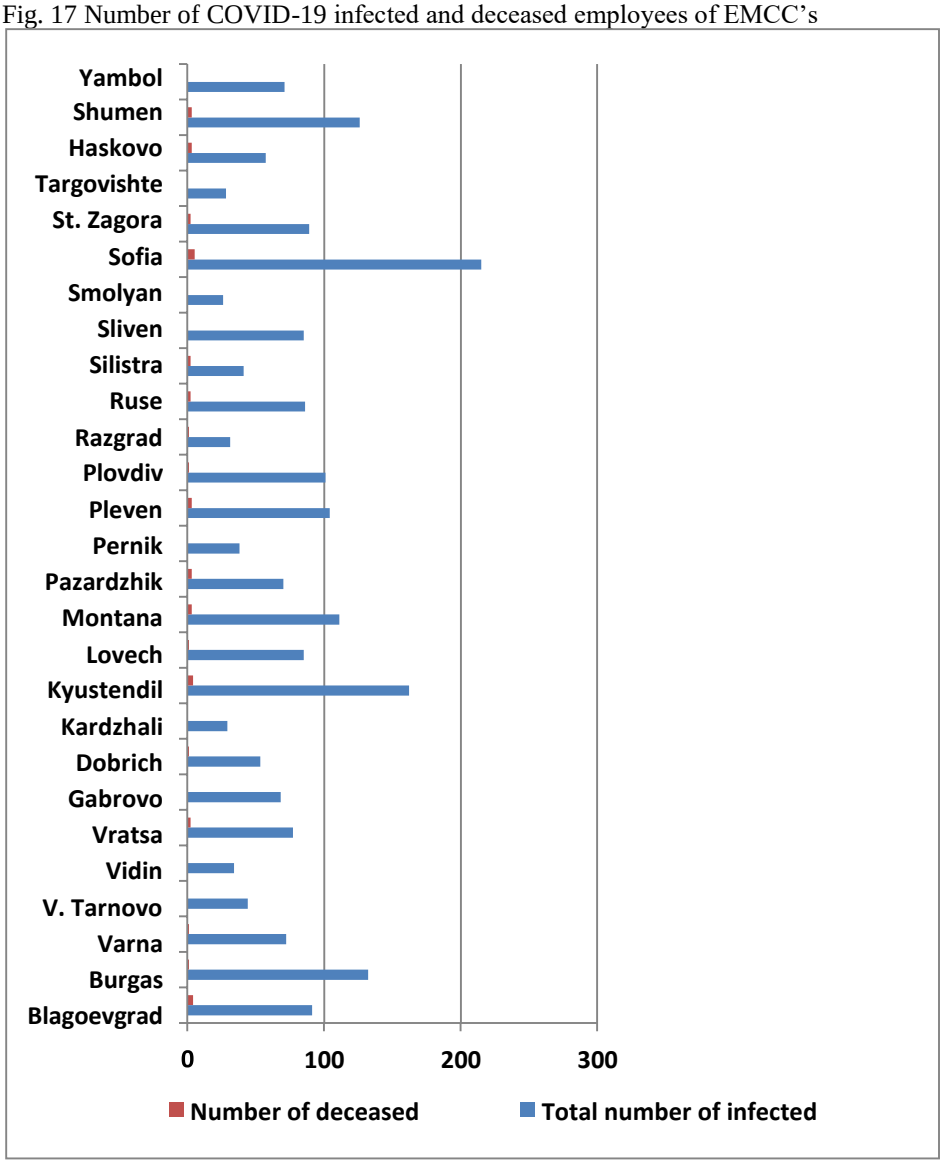
Personnel at the EMCC with COVID-19

The total number of infected employees in the EMCC for the period is 2,126 people. Out of these, 412 were doctors (19.38%) and 1,714 were other staff (80.62%). Relative to the total number of personnel as of 31.05.2021, the proportion of infected staff is 32.65%, or every third staff member was infected. The proportion of infected doctors out of all doctors is 36.49% and is higher than the proportion of infected other staff at 31.85%. The highest number of infected employees was

registered in the EMCC-Sofia (215 people), Kyustendil (162 people), Burgas (132 people) and Shumen (126 people). The lowest numbers were in Smolyan (26 people), Targovishte (28 people) and Kardzhali (29 people).

The number of deceased COVID-19 staff is 42, including 12 doctors and 30 other staff. The fatality rate among all staff with COVID-19 is 1.98%, higher for doctors (2.91%) compared to other staff (1.75%). There were no deceased employees in 9 EMCC's (Vidin, Targovishte, Sliven, Gabrovo, Kardzhali, Veliko Tarnovo, Pernik, Yambol and Sliven). In EMCC-Sofia 5 employees died, 4 employees in both Blagoevgrad and Kyustendil, and in the remaining EMCC's – 1-2 employees each. (Figure 17)

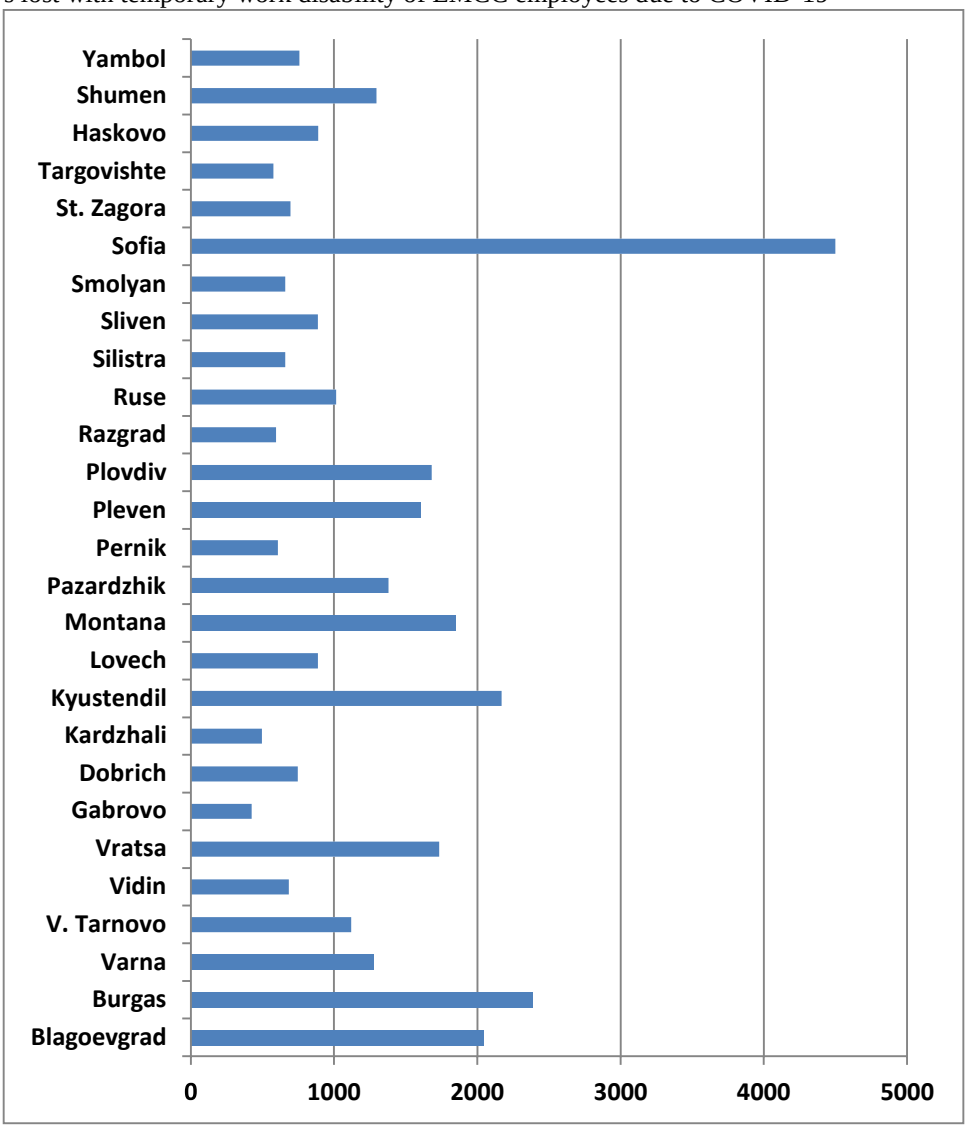
Fig. 17 Number of COVID-19 infected and deceased employees of EMCC's



Source: MoH

The total number of days lost due to temporary work disability through COVID-19 for all EMCC employees for the period is 33,636 days, which is high and has a negative impact on the operations of the centres. The highest number of days lost is for the employees of the EMCC-Sofia (4,500 days). This is followed by Burgas (2,387 days), Blagoevgrad (2,045 days), Kyustendil (2,169 days) and Montana (1,848 days). The lowest value of this indicator is reported in Gabrovo (425 days) and Kardzhali (497). (Figure 18)

Fig. 18. Days lost with temporary work disability of EMCC employees due to COVID-19



Source: MoH

Material-technical base

The total number of ambulances as of 31.05.2021 in the emergency medical care centres is 816. The largest number is in the EMCC-Sofia (115), in Pleven and Varna – 49 each, and in Burgas – 44. The smallest number is in Gabrovo and Targovishte – 14 ambulances each, Shumen – 16, Razgrad – 17 ambulances. Most of the ambulances are equipped (800 ambulances). In 2020, 226 new ambulances fully equipped with medical equipment were delivered to EMCC's, of which 148 with standard drive and 78 with 4x4 drive.

Findings

The EMCC system has a relatively good coverage of the territory of the country with structures of emergency medical care. Staffing levels in the emergency medical services system are relatively good and funding through the state budget for emergency medical services is guaranteed. There has been a great amount of activity during the period: an information and communication system has been set up, a high relative proportion of calls was completed, including for COVID-19, a total of 168 new equipped ambulances have been provided by the MoH, and training of staff from EMCC has been conducted.

In this context, the negatives and challenges that the system faced in the period under review become apparent. According to the Bulgarian Hospital Association, the COVID-19 pandemic was marked by a lack of a comprehensive strategy for dealing with the health crisis, and currently a comprehensive strategy and unified approach is also lacking in providing financial support and preparations for future pandemics.

The negatives in other structures of the health system reflect on the emergency care, which by regulation must be faultless for every patient who has self-identified as an emergency case. Emergency care also bears the consequences of the failures of the health insurance model. Due to the inadequate development of round-the-clock care for insured patients, emergency care also covers their treatment. Urgent care is used as a free way of medical and diagnostic treatment and, when needed, as a free round-the-clock access to medical care, including hospital healthcare. All emergency patients, all uninsured patients, and all insured patients who decide to save themselves the cost of outpatient health care consultations are served by emergency care. Its role as a buffer impairs the ability of emergency care to be timely and equitable and makes it a convenient substitute for outpatient and inpatient health care. Running unwarranted calls and examinations consumes time in both outpatient and inpatient emergency care. There is a lack of differentiation of the true emergency patient among all patients judged to be emergent and seeking medical care. The patient in a life-threatening condition increasingly receives delayed medical care whether at an emergency call or in an emergency department. There is disparity and inequity in the population's access to timely and quality outpatient and inpatient emergency care.

The COVID-19 pandemic has severely impacted the workload of the teams, and the large number of infected medical professionals has proven to be a serious challenge in terms of providing sufficient teams.

The analysis of the emergency care system shows imbalances in provision and usability. There are significant differences in the use of teams, available financial resources and the volume of activity. The ambulance system continues to carry out a significant volume of activity related to activities that do not fall within the scope of specific emergency care activities, such as blood sampling for alcohol and drugs, etc.

There is a lack of communication between outpatient care teams and emergency teams from hospital portals. Real-time communication between the specialists from the medical facilities and those from the EMCC’s is mainly done by landline (direct or through the hospital's switchboard) or simply not done due to lack of it, which delays the patient's admission (or deprives him/her of it) to the most appropriate medical facility for his/her condition.

At the beginning of the pandemic, there was no uniform protocol for the conduct of the medical staff at the EMCC's due to the unknown and unexpected occurrence of the disease. There was a lack of appropriate personal protective equipment, including sufficient disinfectants, for the same reasons—lack of preparedness for rapid and adequate responses to this disease.

A shortage of doctors and paramedics and a worsening age structure are emerging. More overtime is being worked and retirement age medics are being contracted.

As of the end of May 2021, a reduced number of personnel in the EMCC's (of other staff excluding doctors) is observed compared to the beginning of the 15-month period under review, which can be related to some extent to turnover, infected, deceased and staff with complications from the disease, etc. A relatively high number of personnel were infected with COVID-19, one in three, with a total of 42 staff who died from the disease, including 12 doctors.

The issues related to hospitalization are: prolonged stay of patients in ambulances due to low throughput of emergency departments, and a lack of beds at the peak of the pandemic, which slows down the teams of the centres. There is a lack of adequate statistics on hospitalized persons in emergency medical care provided at the EMCC's due to the lack of a targeted data collection system beyond those passing through the emergency departments of the hospitals, which often do not meet the criteria of urgency. This results in an inaccurate number of persons hospitalized by the EMCC's.

In some centres the building stock requires renovation and repair. An insufficient number of equipped ambulances has also been identified. Some of the medical equipment used by the mobile teams is considerably depreciated and cannot provide adequate emergency care capabilities. In the period under review, some EMCC's (Razgrad and Shumen) did not receive a single new ambulance, while others received up to 3 ambulances.

General and pandemic-related issues of the individual EMCC's by districts

Blagoevgrad

General: poor building stock; the new construction of the EMCC has been stalled due to legal proceedings; there is no active reception room in the hospital, all patients transported by the medical teams of the EMCC-Razlog, EMCC-Yakoruda and EMCC-Bansko, as well as outpatients, are consulted in the facility, which extremely strains the activity and hinders the work of the medical teams on duty; shortage of doctors and paramedics, while the working paramedics are of pension age.

Pandemic-related: a shortage of medical staff due to Covid-19 at the BEMC-Blagoevgrad and BEMC-Razlog in November 2020; a shortage of medical staff due to Covid-19 disease at BEMC-Gotse Delchev in March 2021; the sanitary vehicles without oxygen are old UAZ models and are not used for patient care.

Burgas

General: due to the high number of calls and the need for the simultaneous processing of the information received from them in the Regional Coordination Centre (RCC), some issues occurred with the communication and information system, which necessitated the use of the back-up communication system to avoid a problem in communication with patients and with the District Centre 112 (at the moment the communication and information system has been completely upgraded, including the electric power supply); a shortage of medical staff due to a lack of people willing to work in the EMCC, which leads to difficulties in drawing up a monthly work schedule and staffing medical teams—this requires additional work (Article 110 and Article 259 of the Labour Code), overtime, as well as concluding employment contracts with medical staff who have acquired the right to a retirement pension, as some of them refuse to work overtime.

Pandemic-related: from March to June 2020 – recurring problems in supplying PPE and disinfectants; October – a problem in working out a work schedule for the BEMC and working understaffed due to ill and quarantined medical staff; from November – a problem with the drafting of the BEMC work schedule and working understaffed due to ill and quarantined medical staff, a delayed admission of patients to the inpatient care facilities, which are overloaded, leading to a bottleneck in the rhythmic activity of the BEMC and a resulting high number of delayed calls; January – a delayed admission of patients to hospital care facilities which are overloaded, resulting in a bottleneck in the rhythmic activity of the EMCC and a resulting high number of delayed calls.

Varna

Pandemic-related: October-December – problems with hospitalization of patients; delay in the execution of missions due to long waiting times for the teams of CSMP-Varna in front of the coordination centre at the University Hospital "St. Marina" and due to the increased number of alerts related to COVID-19; March-April – a delay in the execution of missions due to the increased number of alerts related to COVID-19.

Veliko Tarnovo

General: a lack of candidates for work—both doctors and paramedics; difficulties of staff with electronic communication; high average age of workers leading to frequent and prolonged absenteeism; unrenewed building stock.

Pandemic-related: at the beginning – difficulties with the provision of PPE and disinfectants;September – problems with the provision of oxygen; October-November – difficulties with the work schedule due to ill employees; from December to May – prolonged stay of patients in ambulances due to low throughput capacity of the Emergency Department.

Gabrovo

Pandemic-related: in the beginning – difficulty in procuring personal protective equipment; from

June 2020 to May 2021 – difficulty in securing work schedule due to sick employees and planning annual leave.

Kardzhali

*Pandemic-related**:*** a lack of sufficient personal protective equipment at the start of the period; March 2021 – increased number of addresses related to COVID-19, and transportation of quarantined and COVID-19 patients (to and from the facility).

Pleven

General: November-December 2020 and March 2021 – delay of the teams in handing over the patients to the emergency receptions at the hospitals.

Pandemic-related: the same period – difficulty in hospitalization of patients.

Plovdiv

*General: a s*hortage of medical staff throughout the period.

Pandemic-related: March to June 2020 – difficulties in providing personal protective equipment; refusal of some GP's to serve Covid-19 patients; July to September – refusal of some GP's to serve Covid-19 patients; October to December – lack of sufficient beds for hospitalisation of Covid-19 patients; refusal of some GP's to serve Covid-19 patients; January to May 2021 – refusal of some GP's to serve Covid-19 patients.

Razgrad

General: during the period, EMCC-Razgrad did not receive any new ambulances.

Pandemic-related: the methodology for incentivising frontline work is not appropriate and is unfair.

Ruse

General: in the beginning – a lack of PPE.

Stara Zagora

General: Insufficient staffing and incomplete staff positions to comply with the requirements of the medical standard "Emergency Medicine", approved by Ordinance No 3 of 6 October 2017.

Silistra

General: March to October – increased subsistence amounts associated with procuring PPE for the entire period of the declared state of emergency and epidemic emergency;November – large number of medical professionals infected with Covid-19, increased overtime hours, and pronounced staffing shortages; December-January – increased overtime and pronounced staffing shortages; February – increased maintenance amounts related to PPE procurement for the entire period of the declared state of emergency and epidemic emergency; March-April 2021 – increased

overtime hours and pronounced staffing shortages; May – increased amounts for maintenance related to the procurement of PPE for the duration of the declared state of emergency and epidemic emergency.

Montana

Pandemic-related: from April 2020 – delayed admission of patients to hospital wards.

Targovishte

General: shortage of doctors and paramedics.

Pandemic-related: due to ill employees from COVID-19 in EMCC-Targovishte, it was needed to redirect medical teams from neighbouring BEMC's to EMCC-Targovishte to perform the activities.

EMCC Vidin, Vratsa, Dobrich, Kyustendil, Lovech, Pazardzhik, Pernik, Smolyan, Sofia, Haskovo, Sliven, Shumen and Yambol have not indicated any problems.

To improve the functioning of emergency medical care, the following is necessary:

- a growing public dissatisfaction and health insecurity with the quality of health services provided, including emergency care;
- continuously increasing financial costs of health care in the face of deteriorating public health indicators;
- the country's commitments as a member of the European Union to ensure the quality of healthcare, especially in emergency care, given the increasing mobility of citizens within the EU;
- a growing need for emergency medical system preparedness to respond to epidemics, natural disasters and catastrophes.

To improve the functioning of emergency medical care, the following is necessary:

- The functional integration of the two main components of the system—outpatient and inpatient emergency medical care—to allow continuity of service to the emergency patient and to ensure the necessary investments in the development of human resources, infrastructure and material and technical support to ensure the timeliness and quality of the care provided.
- Developing the model of the emergency medical care system on the basis of the identified strengths, opportunities and identified problems to create conditions for its sustainability.
- The development and improvement of the knowledge and skills of those working in the EMCC, given their work in conditions of time and information deficit, which will lead to a rapid and adequate response from the moment of receipt of an emergency signal until the patient is discharged in a stable, non-life-threatening condition.
- Optimal provision of staff and recruiting young people to the specialty of emergency medicine through the use of different methods.
- The development of telemedicine as an important element of medical control, which will allow equal access of patients to highly qualified care.

- Providing all centres with standardised sanitary transport that will improve and standardise working conditions and ensure a more equal treatment of patients.[4]

4 Concept for development of the emergency medical care system 2014-2020.

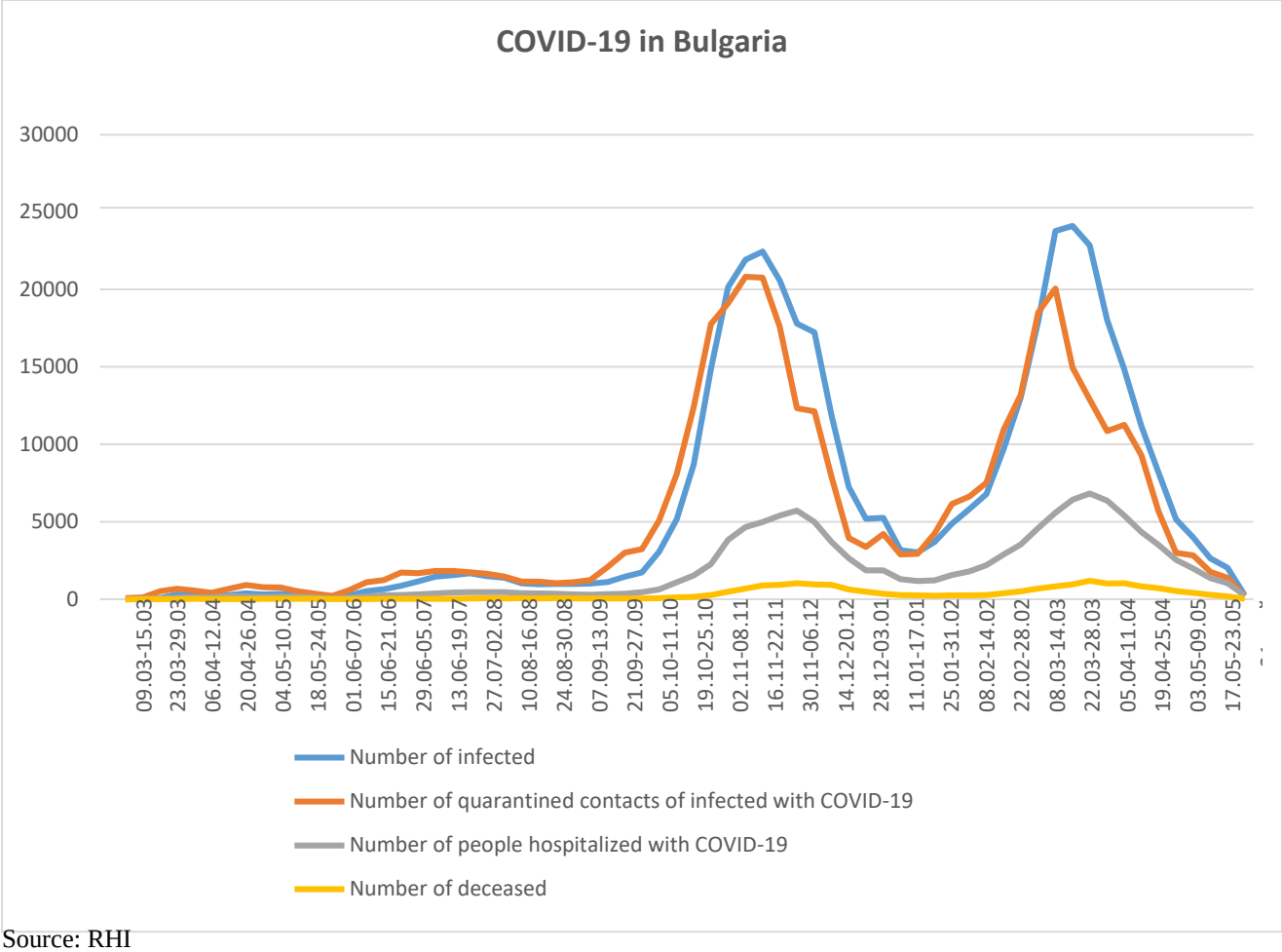
Part 3

Analysis of the activities of outpatient primary care

Dynamics of the COVID-19 pandemic in Bulgaria

Figure 19 shows the pandemic dynamics for the period March 2020-May 2021 by four indicators: number of infected, number of quarantined contacts of infected, number of Covid-19 hospitalisations, and number of deaths.

Fig. 19

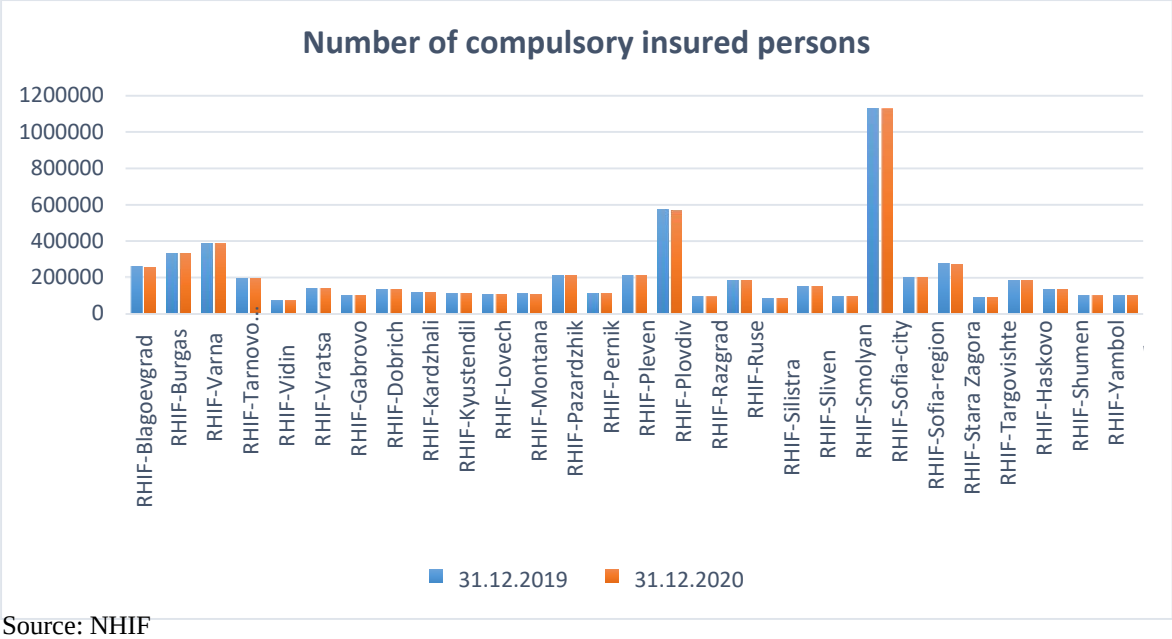


Source: RHI

Number of compulsorily insured persons

Based on data from the National Health Insurance Fund (NHIF), the number of compulsorily insured persons (CIP's) with continuous health insurance rights for 2020 decreased by 1.43% or by 84,159 persons compared to 2019. (Figure 20)

Fig. 20



Source: NHIF

The trend by age is as follows:

- 0-18 years – decrease by 0,98% or 11,834 persons less;
- 18-65 years – decrease by 2,06% or 65,7430 persons less;
- over 65 years – decrease by 0,51% or 7,614 persons less.

On the basis of the above data, there is a clear downward trend in the number of CIP's in all ages and in all districts. The largest decrease in the number of CIP's in terms of percentage is observed in Targovishte (3.45% or 3,099 persons), Vidin (2.99% or 2,158 persons), Lovech (2.51% or 2,680 persons), Razgrad (2.43% or persons), Kyustendil (2.36% or 2,546 persons) and Silistra (2.22% or 1,884 persons). Correspondingly, the smallest decrease in the number of CIP's was in Sofia-city (0.515% or 5,820 persons) and in Kardzhali (only 0.519% or 616 persons). This decrease should be taken into account if a decrease in the examined indicators within 1.5 to 2% is observed.

To assess GP activity for the period 1 March 2020 to 31 May 2021, a comparison is made between GP activity for the periods March 2019-February 2020 and March 2020-February 2021, after which the data for the months of March and April 2021 are analysed against the average monthly score for the year prior to the pandemic, derived from the total number of GP activities for the twelve-month period March 2019-February 2020 divided by 12. The data presented are obtained from the NHIF, the NSSI and all the RHI's in the country.[5]

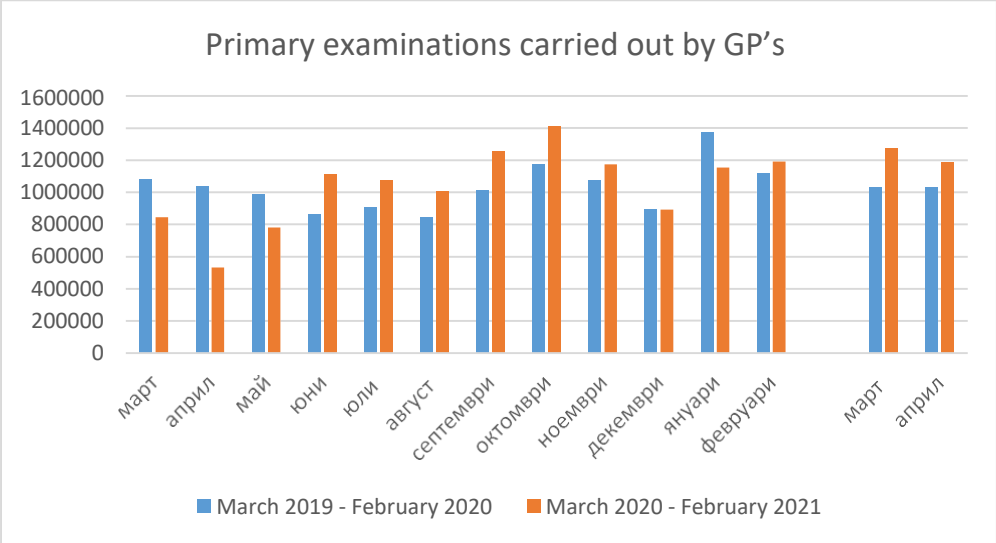
Performed examinations by type

The data show that the total number of primary examinations (including consultation, dispensary examination, child and maternal health and at the request of the Territorial Medical Expert

5 For the month of May 2021, at the time of writing the report, no data has been received from the NHIF and NSSI.

Commissions – TMEC's) carried out by GP's during the pandemic in the period March 2020-February 2021 did not decrease compared with primary examinations carried out in the period March 2019-February 2020. The lowest number of primary examinations were performed in March, April and May, with significant decreases of 22% in March, 49% in April 2020 and 21% in May 2020. There was also a decrease of 15% in January 2021, but all other months saw a significantly higher number of primary examinations compared to the one-year prior period, with the highest number of primary examinations in June (28%), September (23%) and October (20%) 2020. More primary examinations were also performed in March and April 2021 compared to the pre-pandemic average. (Figure 21)

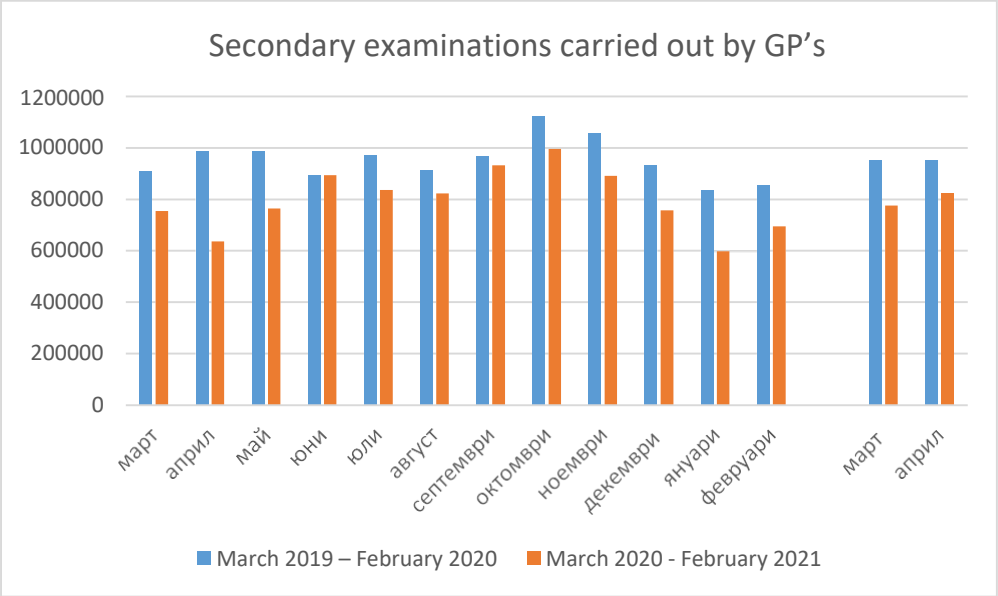
Fig. 21



Source: NHIF

This is not the same story when it comes to secondary examinations , which are down 16% for the period March 2020-February 2021 compared to the previous one-year period. The data show that there were fewer total examinations in all months of the period, with the fewest secondary examinations in April and May 2020, 35% and 23% fewer respectively compared to the pre-pandemic period, and 28% fewer in January 2021. (Figure 22)

Fig. 22

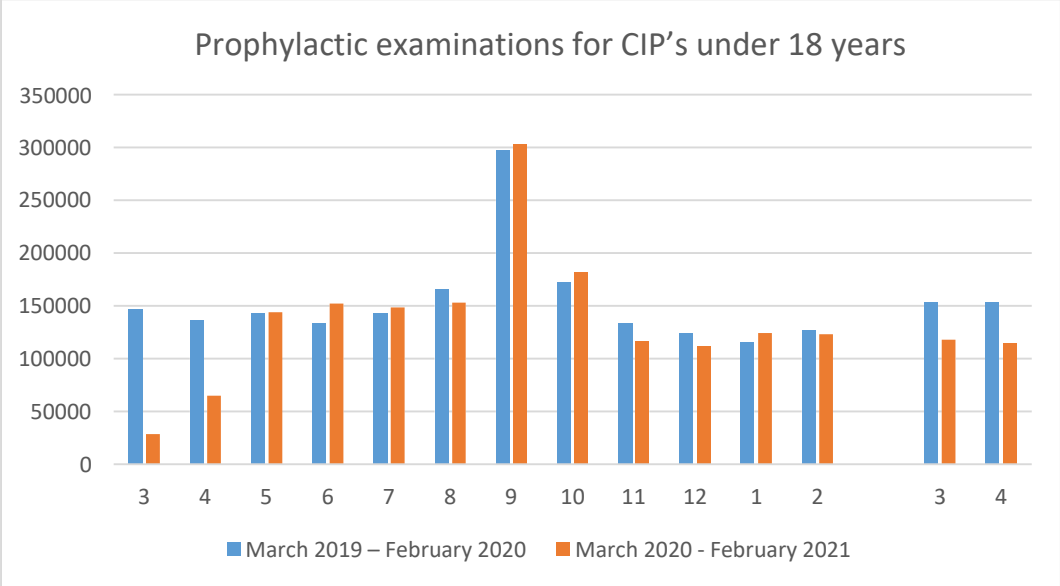


Source: NHIF

Prophylactic examinations of persons under 18 years

For prophylactic examinations of persons under 18 in the period analysed from March 2020 to February 2021, there was a 10.3% decrease in the total number of prophylactic examinations compared to the previous one-year period (March 2019-February 2020). (Figure 23)

Fig. 23



Source: NHIF

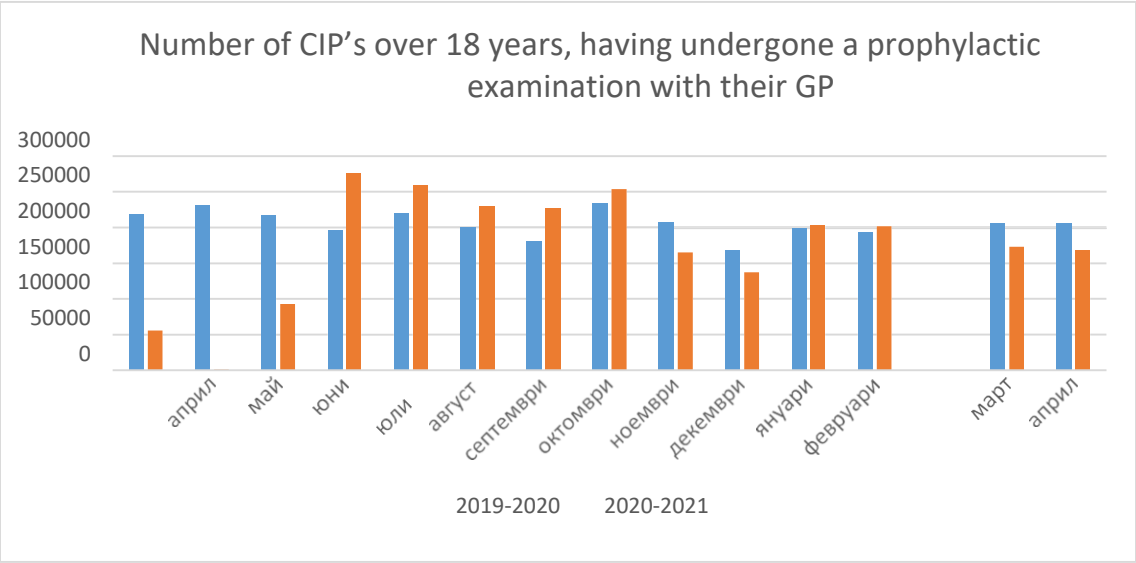
The months during the pandemic period where no or very low percentages of prophylactic examinations took place were March 2020 and April 2020, where the reductions were by 80% for March and 52% for April compared to the same months of the preceding one-year period. The analysis of GP activity in terms of prophylactic examinations for March and April 2021 also shows a decrease, with March down by 23% and April down by 25% compared to the average monthly

number of prophylactic examinations for children in the pre-pandemic period.

Prophylactic examinations of persons over 18 years

The data show that in terms of prophylactic examinations of compulsorily insured persons over 18 years, there is a decrease in the total number of prophylactic examinations by 15% compared to the previous one-year period (March 2019-February 2020). The months in which no or a very small percentage of prophylactic examinations took place during the pandemic period were March 2020, when examinations accounted for only 25.6%, and May 2020, 42% compared to the same months of the preceding one-year period, while no prophylactic examinations were carried out in April for CIP's aged 18 years and over—the total for the whole country was 0.5%. (Figure 24)

Fig. 24

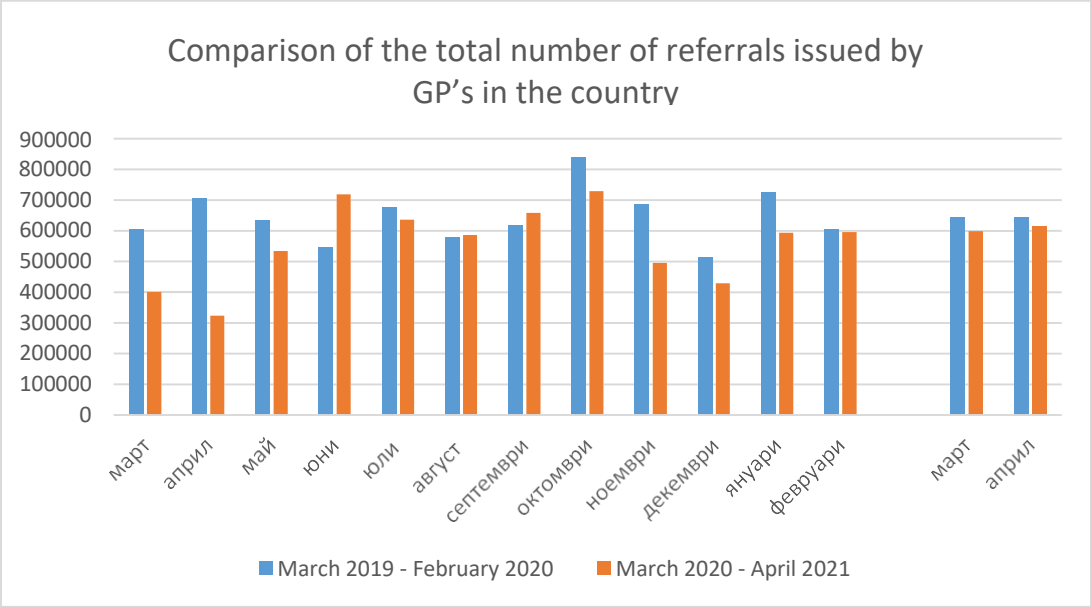


Source: NHIF

Referrals issued by GP's

In the period March 2020-February 2021 there can also be observed a decrease in the total number of referrals issued by all GP's in the country by 13.3% compared to the period March 2019-February 2020. It is important to note that in both the months of March and April 2021, referrals made by GP's nationally were lower than the average for the period in March 2019, by 7% for February 2020 and 4.5% for March and April 2021 respectively. (Figure 25)

Fig. 25



Source: NHIF

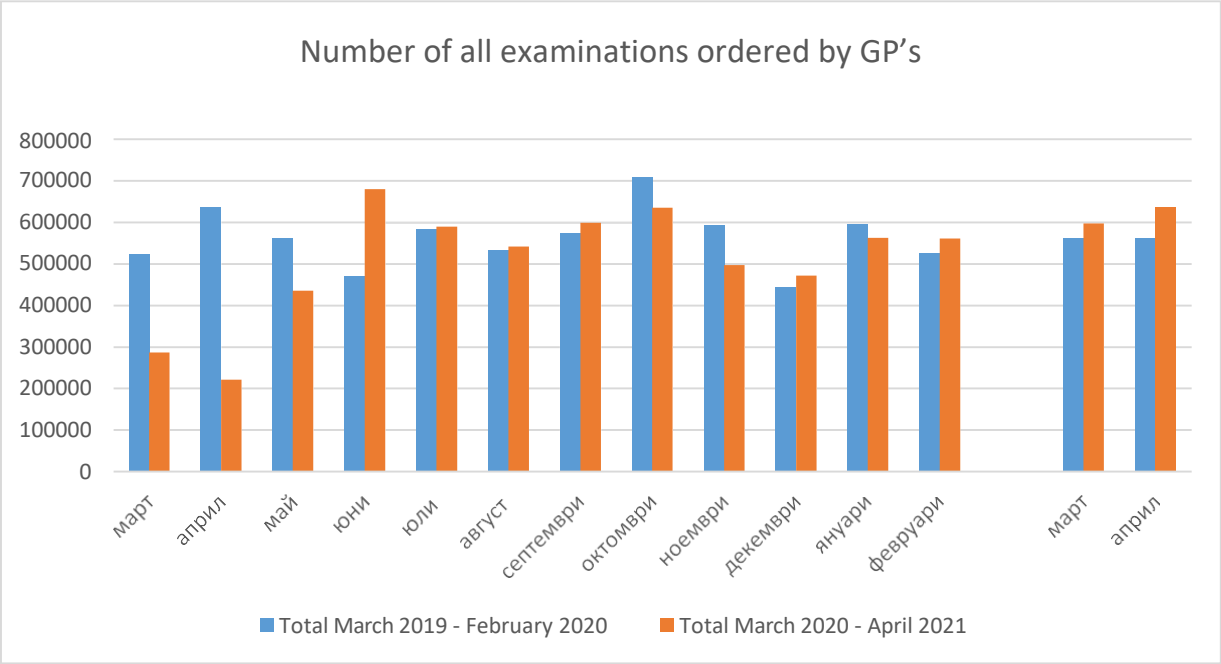
The reduction in referrals issued by GP's is in all likelihood due to a reduction in demand for help during these months, which coincide with the big lockdown following the announcement of the start of the pandemic, as well as the first major surge in the country in November-December 2020 and January 2021.

Appointed examinations by GP's

With regard to the appointment of examinations, there can also be seen a decrease, but the differences between the two comparable periods are smaller. In total for the entire country, the examinations appointed by GP's are by 9.8% less, with the months of April 2020 (65%), March 2020 (55%) and May 2020 (22%) again being the main contributors. A decrease was also seen in the months of October 2020 (10%) and November 2020 (16%). A decrease of 5% has also been observed in January 2021.

It should be noted that in all other months, the system attempts to compensate for this reduction, and especially in June 2020, when there is a significant subsidence of the pandemic in the country, the appointed examinations are 45% more than in the same month in 2019. Interestingly, in the months of March and April of 2021, the appointed referrals by GP's in the country are more than the average for the period March 2019-February 2020 – by 6% in March and 13% in April 2021. (Figure 26)

Fig. 26

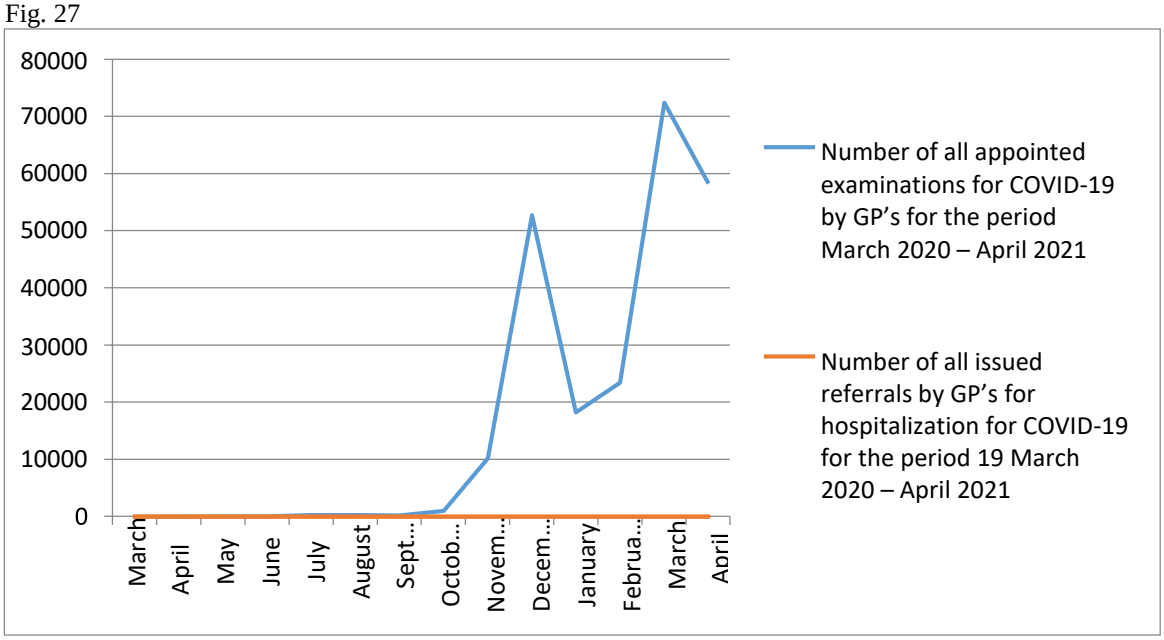


Source: NHIF

Assigned examinations and issued referrals for hospitalisations for COVID-19 by GP's

The data show that, as might be expected, peaks in GP's prescribing tests for COVID-19 are associated with the major pandemic waves in November-December 2020 and March-April 2021. (Figure 27)

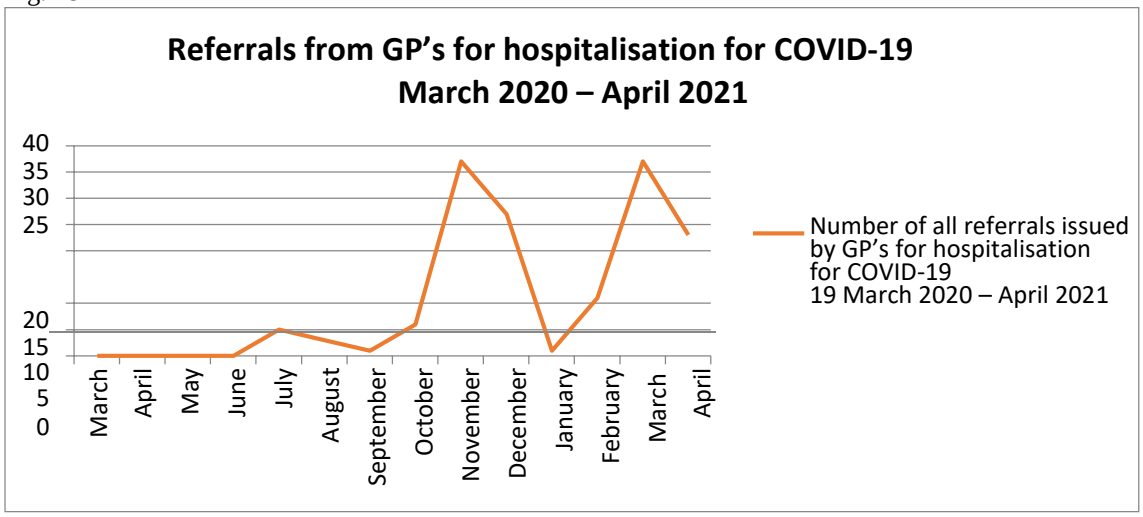
Fig. 27



Source: NHIF

However, in terms of hospitalisations for COVID-19, it can be said that in practice, GP's were hardly involved in the hospitalisation of their patients, because for the entire period analysed, the total number of referrals issued by GP's for hospitalisation for COVID-19 was 151, although here again the largest number of referrals was noted during both waves. (Figure 28)

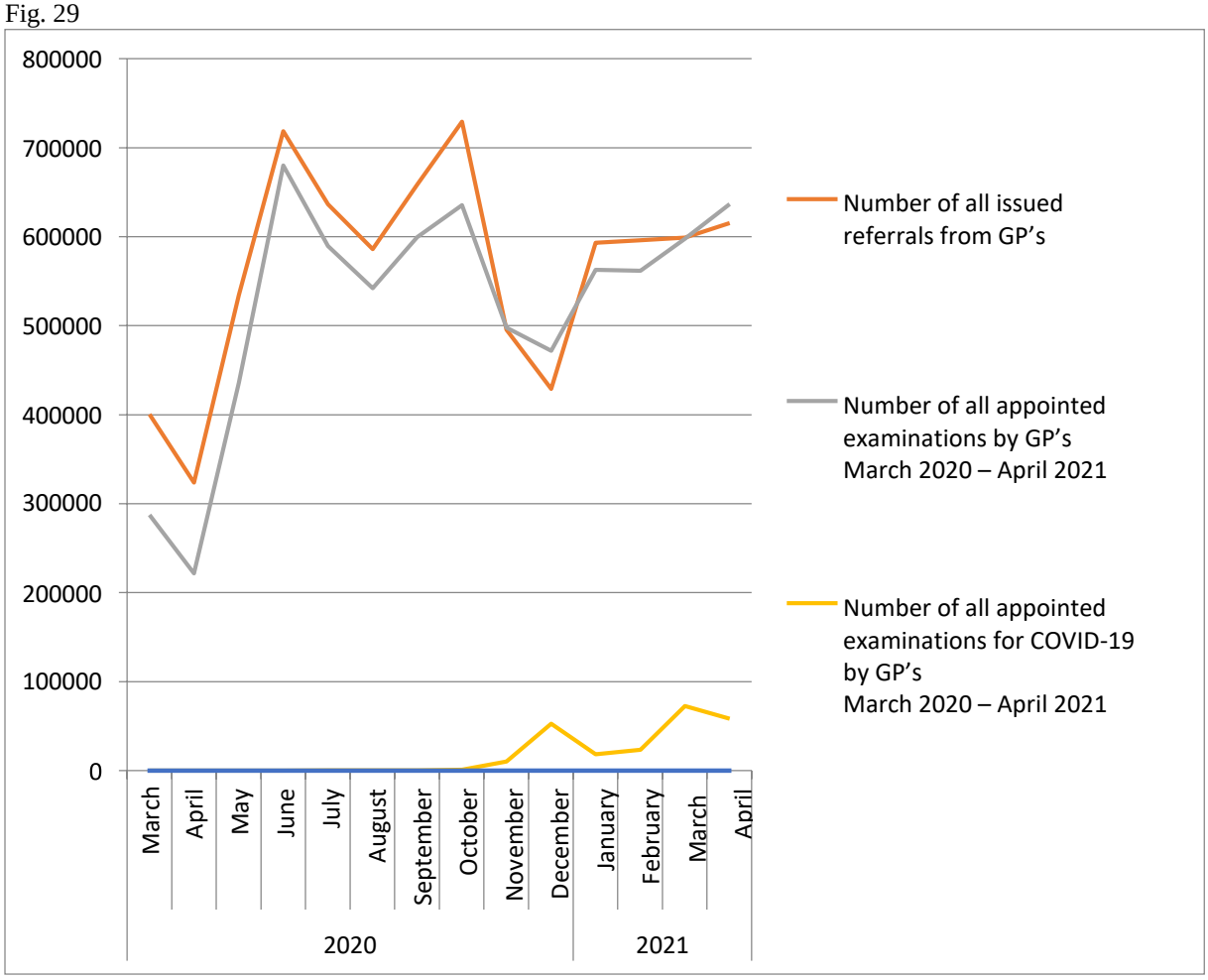
Fig. 28



Source: NHIF

It is also worth comparing the trend of all referrals and all examination appointments by month by the GP's with the trend of referrals and examination appointments for COVID-19 by the GP's. It can be seen that the trend of referrals issued and examinations assigned is opposite to the trend of examinations assigned for COVID-19 and even referrals for hospitalization for COVID-19 (despite their insignificant number) during the two major waves of the pandemic, November-December 2020 and March-April 2021. (Figure 29)

Fig. 29

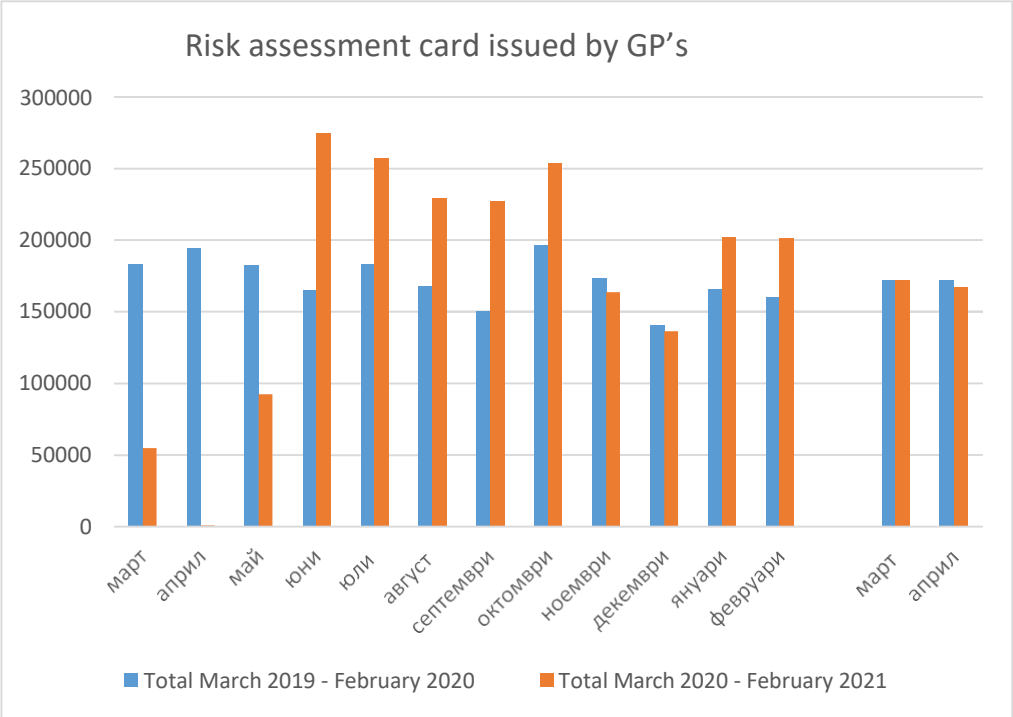


Source: NHIF

Map for the assessment of risk factors for the development of disease

In order to prevent socially significant diseases with health insured persons over 18 years of age, GP's form groups of people with risk factors for the development of disease, and record the results in a "Risk Factor Assessment Card for the Development of Disease". In the period March 2020-February 2021, 2,093,183 risk assessment cards were issued. This compares with 2,064,067 risk assessment cards issued during the same pre-pandemic period, March 2019-February 2020. There was a 1.5% increase in risk cards issued in the period March 2020-February 2021. The number of risk cards issued in March, April and May of 2020 is impressively low, with 70% fewer risk cards issued in March compared to March 2019, 99.5% fewer in April and 50% fewer in May. There is also a slight decrease in trend in November 2020 (5%) and December 2020 (3%), however the number of cards issued in the months of June, July, August, September and October 2020 significantly exceeds the number of risk assessment cards in the same months of 2019. (Figure 30)

Fig. 30



Source: NHIF

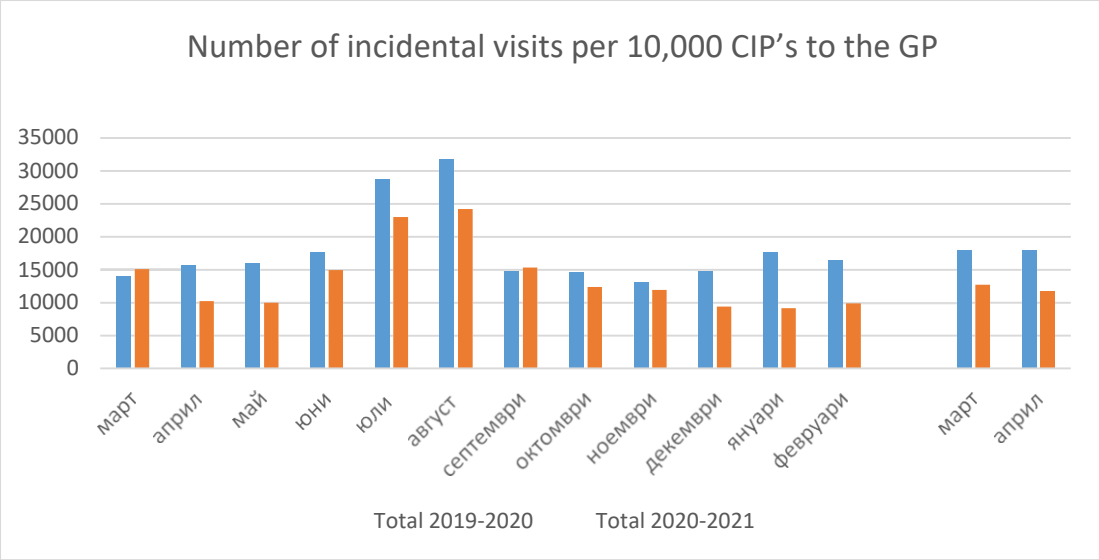
In the last two months for which information is provided by the NHIF, March and April 2021, there was roughly the same number of cards issued relative to the average monthly number for the observed one-year period prior to the pandemic, with a slight decrease of 3% in April 2021.

Incidental visits to GP's

During the analysed period (March 2020-February 2021), the value of the indicator 'Number of incidental visits per 10,000 CIP's at the GP' is 26% lower, which is an expected result given the high confinement and limited travel and holidays during the pandemic. The most significant reductions in this indicator during COVID-19 were seen in the months of April (35%) and May (38%) 2020, and in the winter of 2020/21 – December 2020 (36%), January (48%) and February (40%). There were also significantly fewer occasional visits in March and April 2021 compared to the average monthly visits for the period March 2019 to February 2020 – reductions of 29% and 34% respectively.

Also, during the period under review, the tendency of the same RHIF's reporting very low values of the indicator continued, while others – four times above the national average, as indicated in the report on the activities of the NHIF for 2019. The trend of the highest number of incidental visits per 10,000 CIP's to be reported by GP's remains in the RHIF-Burgas, the RHIF-Blagoevgrad and the RHIF-Plovdiv is also maintained. The lowest values are found in RHIF-Gabrovo, RHIF-Kardzhali and RHIF-Razgrad. (Figure 31)

Fig. 31

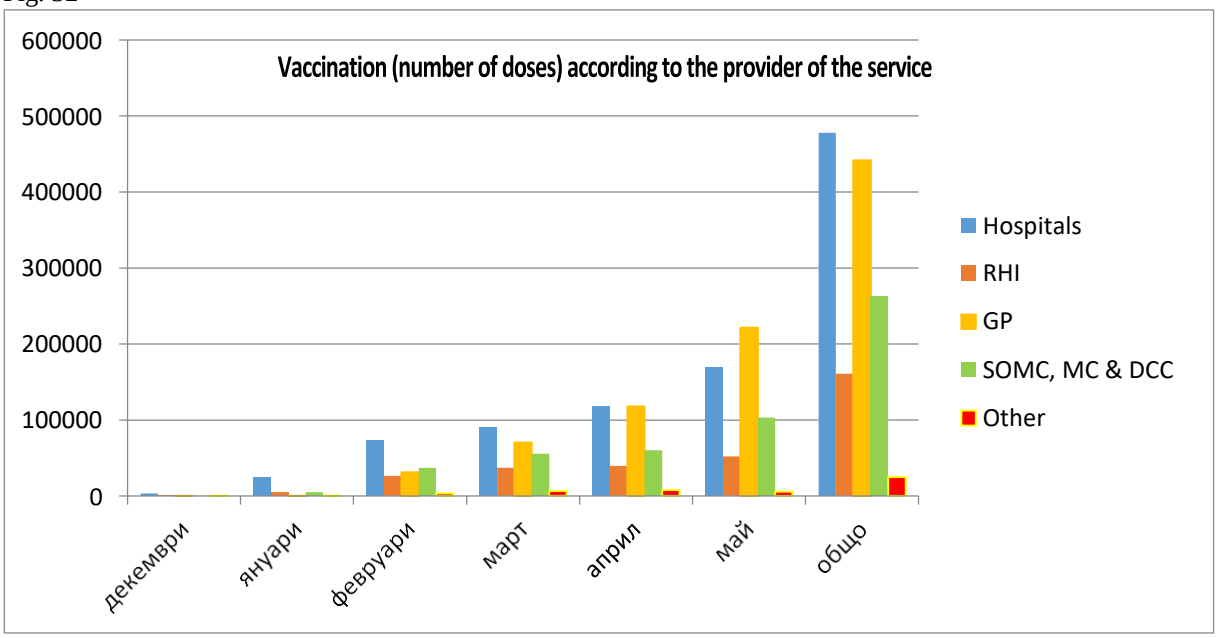


Source: NHIF

Vaccination against COVID-19

The data on the vaccination process in the country and the role of the different units in the health system show that while in the first month GP's contributed to 1% of all doses administered and hospitals to 77%, in May the largest number of vaccines (40%) was administered by GP's and 32% by hospitals. Once they were included in the process, in the last two months of the period, the vaccines administered by GP's levelled off and exceeded the vaccine doses administered by other health structures. (Figure 32)

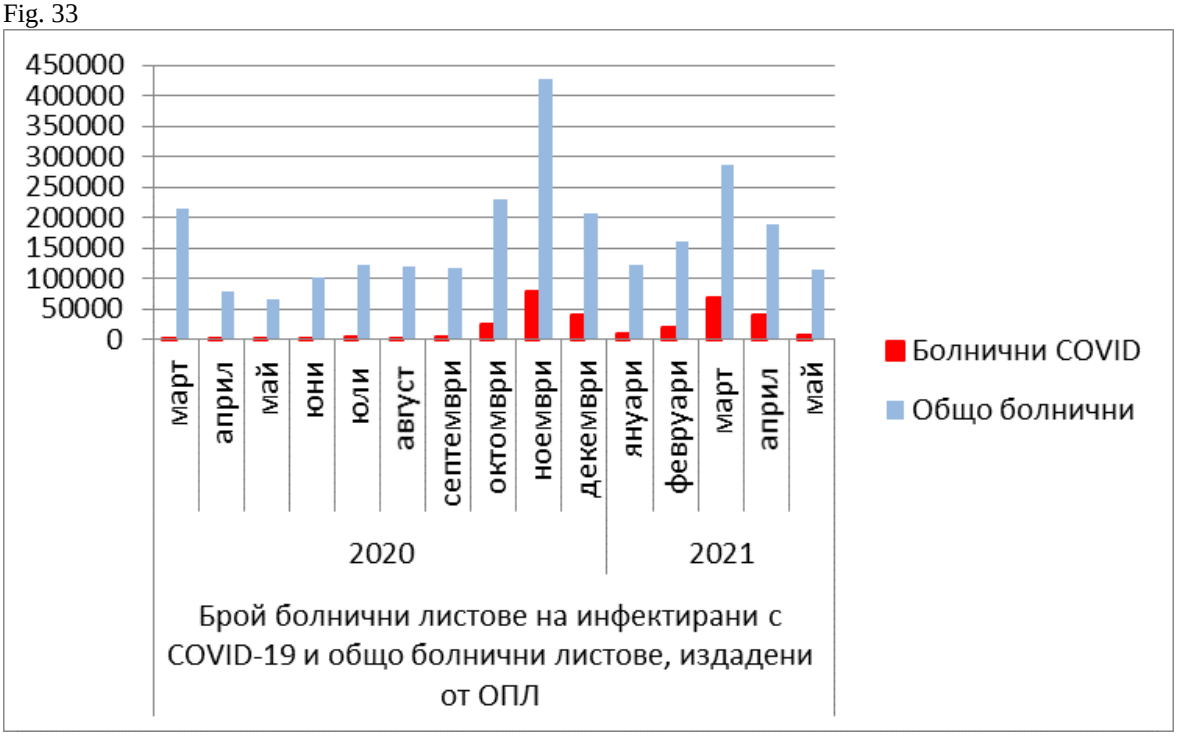
Fig. 32



Source: RHI

To assess the work conducted by GP's during the period analysed, information was also requested from the NSSI on the number of sick notes issued by GP's with codes U07.1, U07.2, B34.2, B97.2 and Z29.B, and the total number of sick notes issued by GP's during the period analysed. (Figure 33)

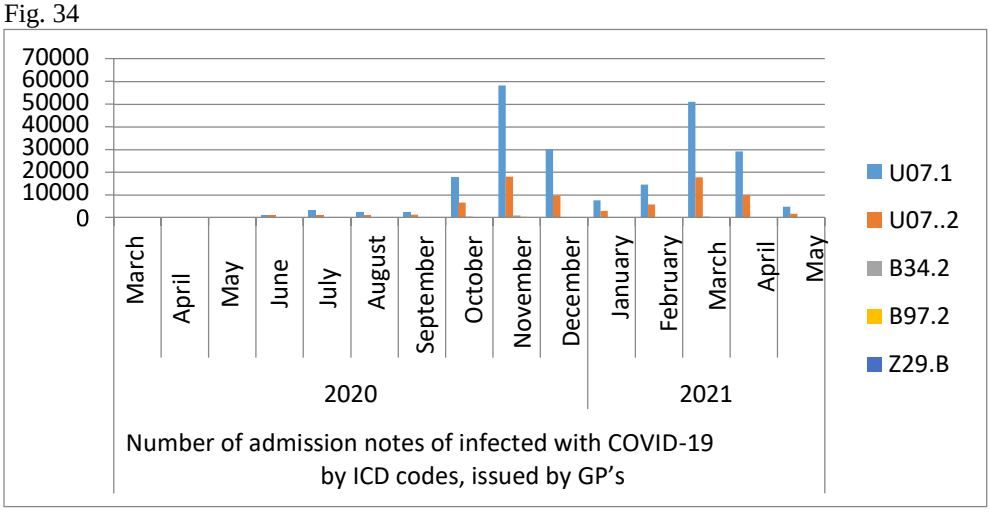
Fig. 33



Source: NSSI

The data show that hospital admissions issued by GP's for those infected with COVID-19 and quarantined contacts total 12% of all hospital admissions issued by GP's in the country for the period March 2020-May 2021, again with most hospital admissions with COVID-19 diagnoses issued during the two major waves of the pandemic, the main codes being the new codes for COVID-19, U07.1 and U07.2. (Figure 34)

Fig. 34



Source: NSSI

Summary and findings

The analysis of the orders issued by the Ministers of Health for the monitored period shows that the scheduled female and child consultations, preventive examinations and preventive immunisations were suspended as of 13.03.2020 by the order of the Minister of Health RD-01-124/13.03.2020, while the scheduled child consultations and the basic compulsory immunisations according to Article 19 of Regulation 15 were reinstated by the order RD-01-225/20.04.2020, specifying also the conditions under which they are reinstated. Order 225 has been amended by Order RD-01-243/29.04.2020, stating that all compulsory scheduled immunisations and re-immunisations under national programmes, as well as preventive examinations for persons under 18 years of age and the measures relating thereto, shall be reimbursed. This explains why in March and April, preventive examinations for persons aged 0 to 18 years were severely reduced and for persons aged above 18 years were practically zero in April.

Overall, the analysis of the individual elements of the Primary Outpatient Medical Care for the period 1 March 2020 to 31 May 2021 shows that the largest declines in GP activities took place in March, April and May 2020, followed to a lesser extent and mainly for prevention activities in the periods of the two major waves—November-December 2020 and March-April 2021. On the one hand, this was driven by the government's initiating actions to stop the spread of COVID-19 after the first cases of the virus were identified in the country, and on the other, by people's fear of visiting GP’s during the pandemic's peak.

At the same time, the comparison between the two identical one-year periods did not fully support the hypothesis of reduced access to GP services throughout the period of COVID-19 prevalence in the country, because in all months of lower prevalence after the first major lockdown, GP’s in Bulgaria actually performed more activities than in the same months in the year before the pandemic.

Part 4

Analysis of the activities of specialized outpatient care

In this part, data on the work of outpatient health care (OPHC) specialists are presented, focusing on the number of examinations of health-insured persons covered by the Health Insurance Fund, as well as on the dispensaries for the main classes of diseases leading to death. Information was requested from the NHIF concerning the activities of specialised outpatient care covering[6]:

- Consultations made by specialists with referral No. 3.
- Conducted dispensary examinations.
- Persons under dispensary observation.
- Prescribed MDA (medical diagnostic activity).
- Prescribed HSA (highly specialised activity).
- Referrals for hospitalizations.

The information obtained was processed in tabular and graphical form and divided into five categories:

First category – the specialties with examinations, tests, etc. under 100 per month. Due to the small number of cases, these specialties are not included in this analysis. This category includes the following specialties:

- Anaesthesiology and intensive care (code 26);
- Clinical toxicology (code 37);
- Clinical immunology (code 45);
- Paediatric clinical haematology and oncology (code 51).

Second category – the specialties with part of the data below 100 were analysed only in the parts with more than 100 activities per month:

- Obstetrics and gynaecology (code 01);
- Clinical allergology (code 02);
- Gastroenterology (code 03);
- Skin and venereal diseases (code 04) and others.

Third category – the specialities for which no information is provided for part of the activities.

- Clinical Allergy and Paediatrics (Code 33).

Fourth category – the specialties for which complete information is obtained, but no data on dispensation is available.

- Physical and rehabilitation medicine (code 23);
- Internal diseases (code 06);
- Infectious diseases (code 07);
- Medical oncology (code 12);
- Psychiatry (code 18);
- Clinical Haematology (code 24);

6 This information does not cover individuals who are self-payers and those who are not health insured.

- Thoracic surgery (code 27);
- Neurosurgery (code 29);
- Vascular surgery (code 31) and others.

Fifth category – the specialties where the entire volume of information has been analysed:

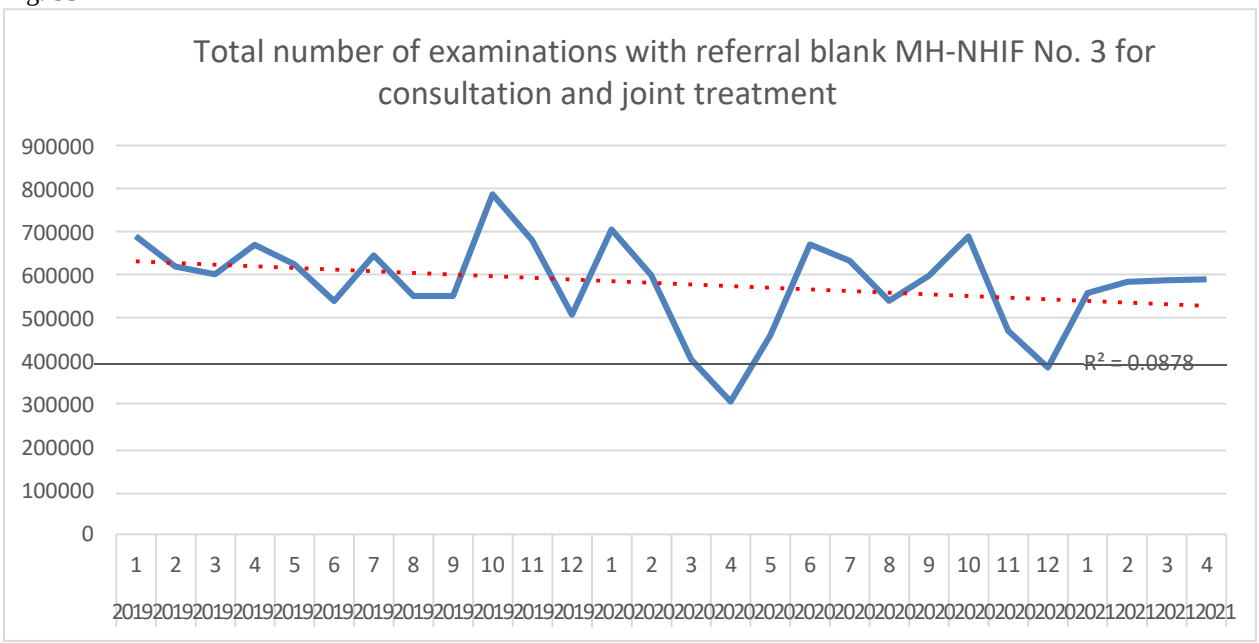
- Endocrinology and metabolic diseases (code 05);
- Cardiology (code 08);
- Nervous diseases (code 10);
- Nephrology (code 11);
- Eye diseases (code 15);
- Pneumology and Phthisiology (code 19).

The set of information is aggregated for the needs and in compliance with the assignment, but it is possible to further disaggregate and to provide data both by specific specialties and by the types of activities they perform.

Overview of the performed examinations and data on the dispensary observations of the SIMP[7]

An analysis of the ambulatory work of all types of specialists operating in outpatient care and having a contract with the NHIF was performed. The information provided by the NHIF covers the period 01.01.2019-30.04.2021. A downward trend in the number of examinations by specialists of insured persons has been observed for the study period. (Figure 35)

Fig. 35

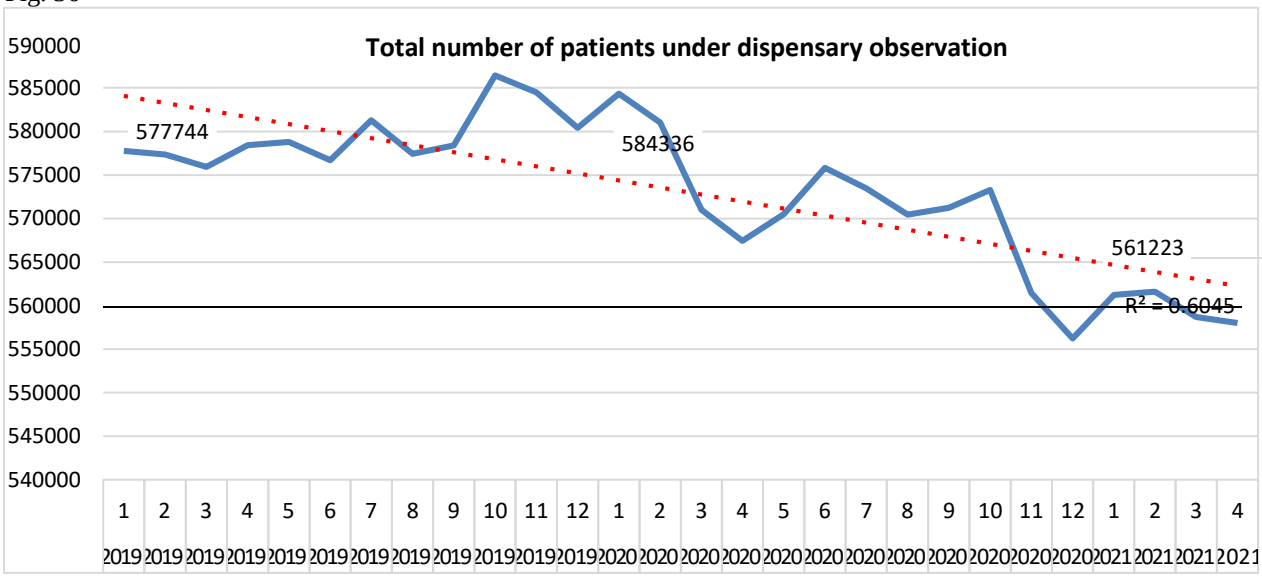


Source: NHIF

7 Data for the period 01.01.2019-30.04.2021, provided by the NHIF. The absolute numbers have been analysed, because when recalculated per 100 000 population, no difference in trends is found.

In the following graph are presented summarized data on the number of persons under dispensary observation in specialized outpatient care in the country. It is noteworthy that for the period 01.01.2020-31.12.2021, the number of people with all chronic diseases monitored by the Specialised Outpatient Medical Care (SOMC) has decreased by about 23,000 people. (Figure 36)

Fig. 36

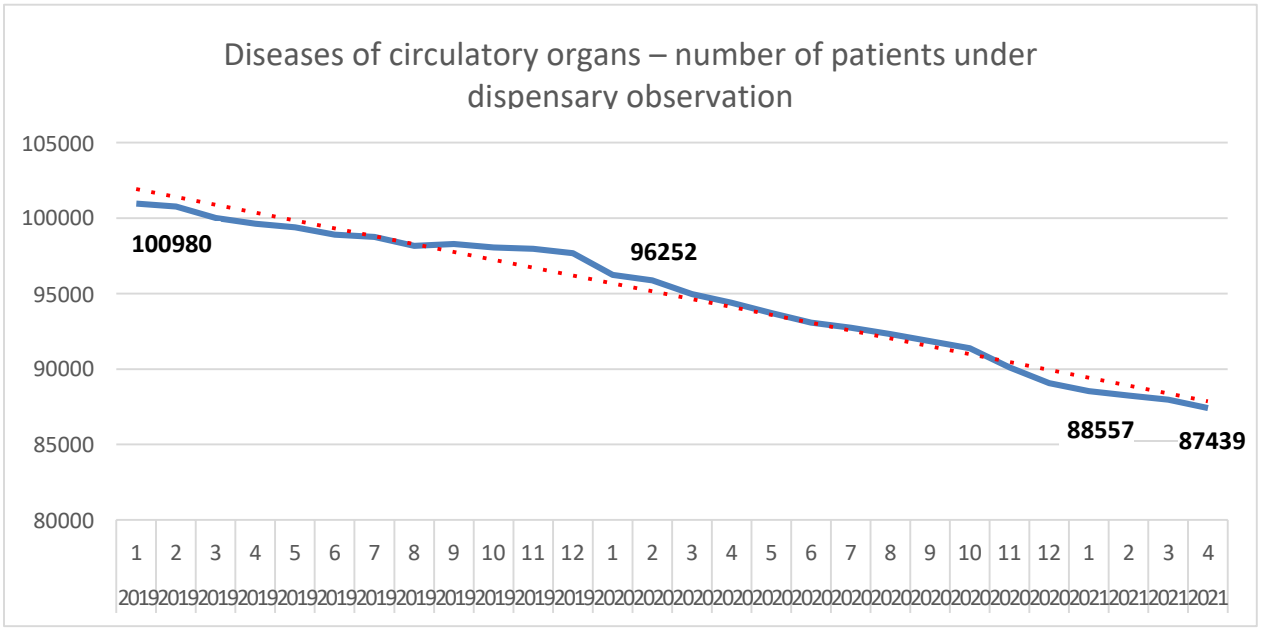


Source: NHIF

Distributed by disease classes (according to ICD-10), the aggregated data for the country show the following values:

- for circulatory organ diseases (I00-I99), the number of dispensary cases in 2020 decreased by about 7,700 (Figure 37);

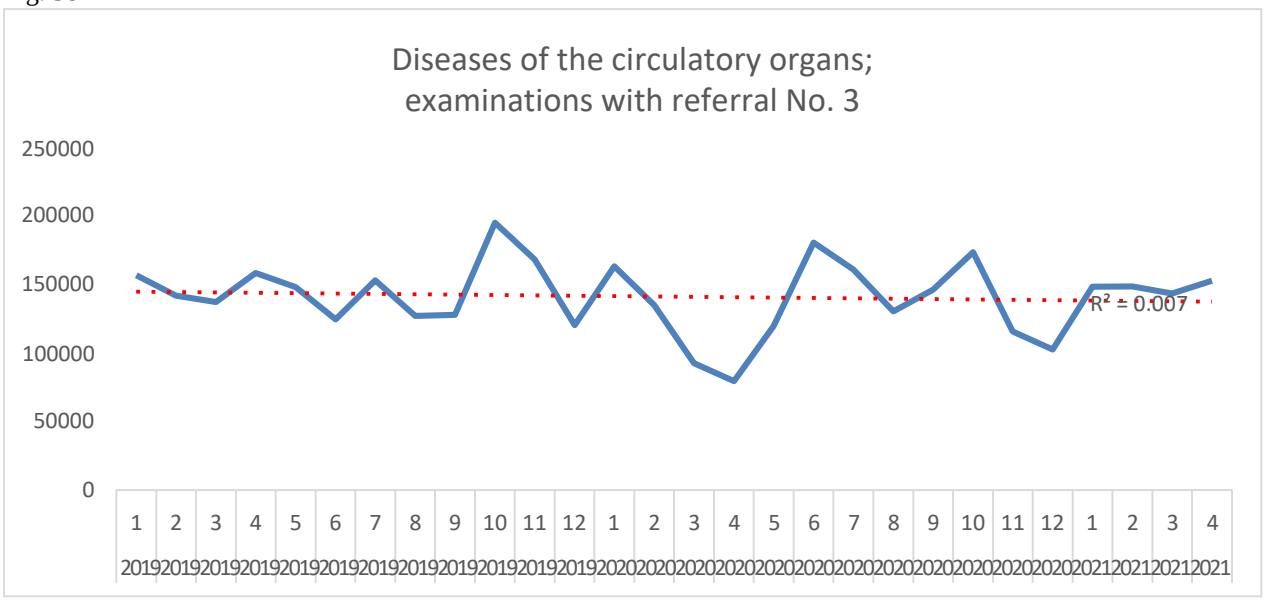
Fig. 37



Source: NHIF

- for the same class of diseases, the trend of consultations performed by specialists is almost constant. There is a significant decline for March and April 2020 and a less severe decline for November and December of the same year (Figure 38);

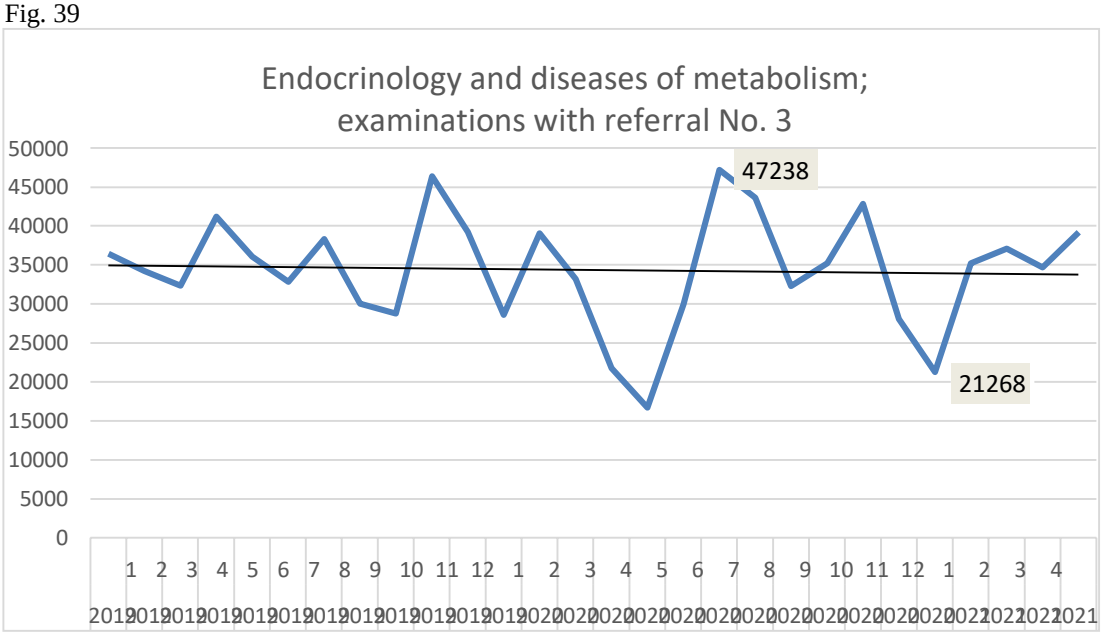
Fig. 38



Source: NHIF

- for diseases of the endocrine system, disorders of nutrition and metabolism (E00-E99) of class IV of ICD-10, the data on consultations and patients under observation are presented in Figure 39;

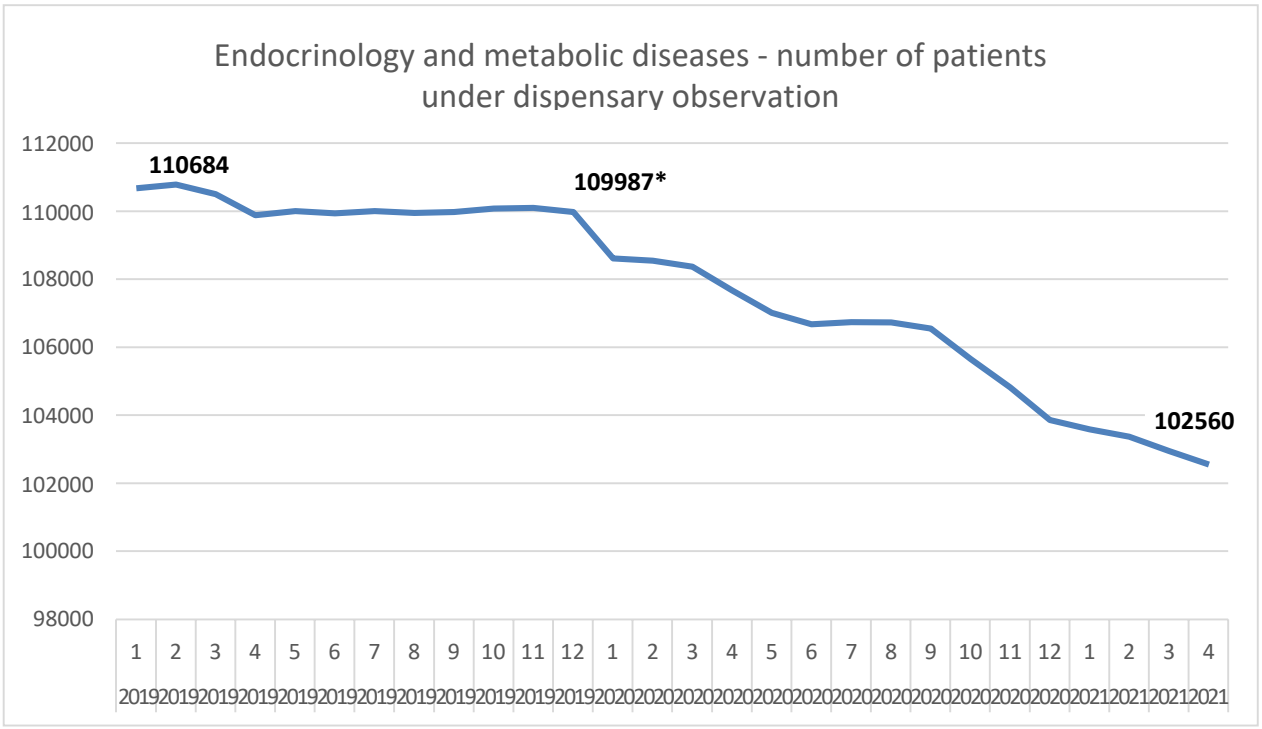
Fig. 39



Source: NHIF

- in this class of diseases, too, a decrease in the number of medically examined patients with endocrine diseases is reported—by about 7,200 people (Figure 40).

Fig. 40

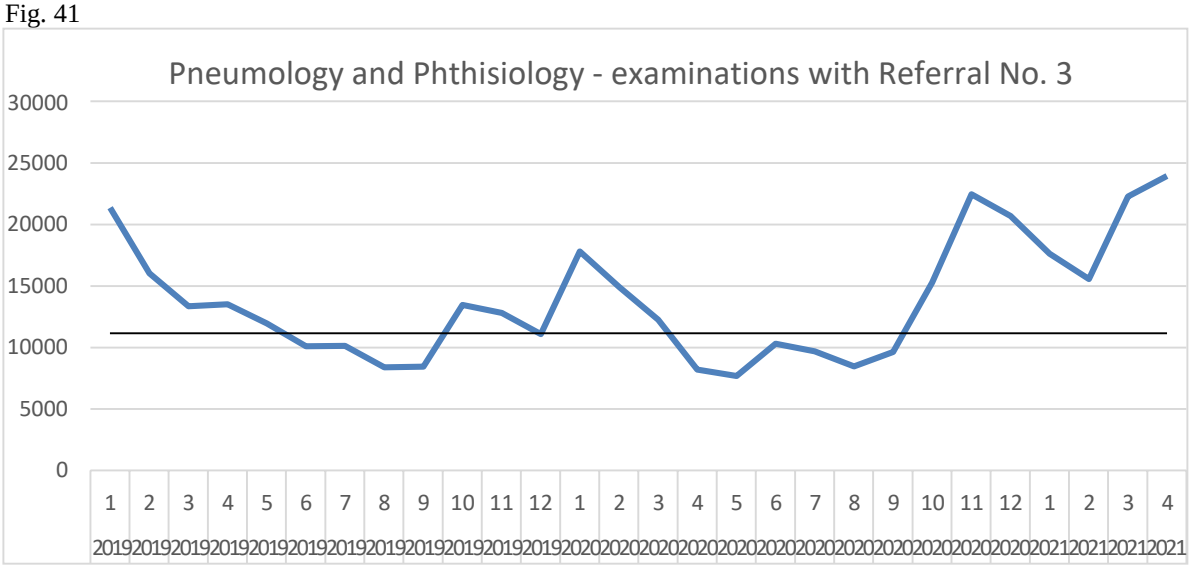


Source: NHIF

***** *In the annual report on the activities of the NHIF for 2019, published on the website of the Health Insurance Fund, it is reflected that the number of dispensed patients for diseases of the endocrine system, eating disorders and metabolism for 2019 is 122,834. The data for 2018 shows the number of persons dispensed at 124,596.*

Class X diseases of the ICD-10 are diseases of the respiratory system (J00-J99). These showed an upward trend for outpatient consultations during the first year of the pandemic. (Figure 41)

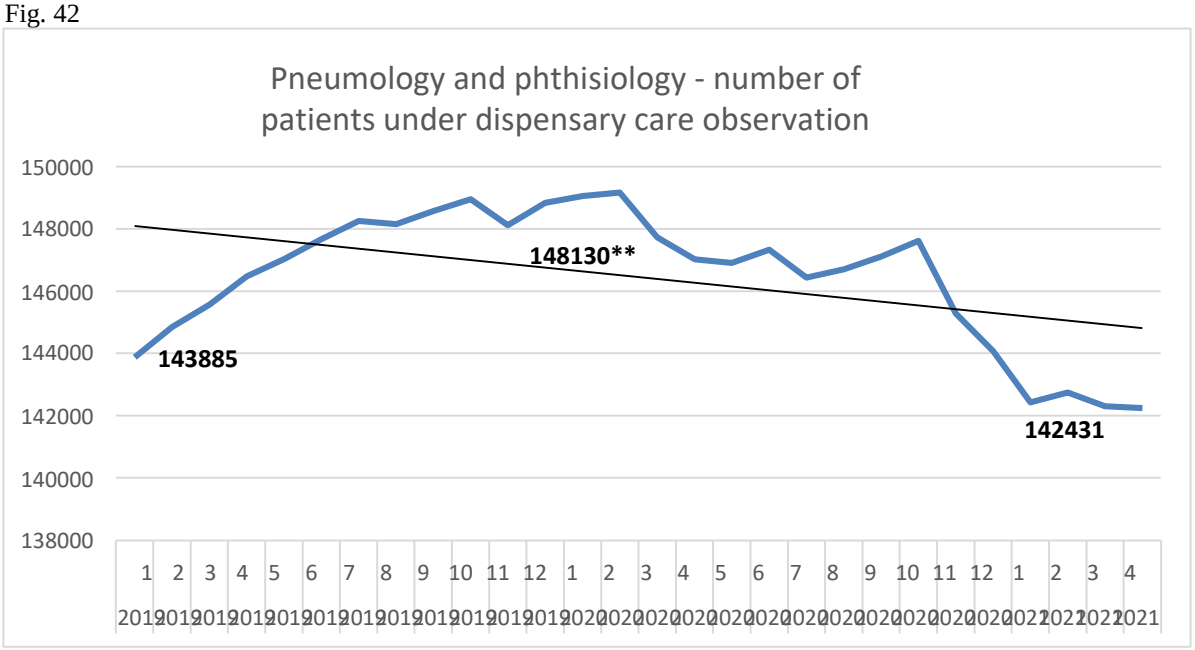
Fig. 41



Source: NHIF

In this class of diseases, too, a reduction in the number of dispensary cases of about 5,700 people is reported. (Figure 42)

Fig. 42

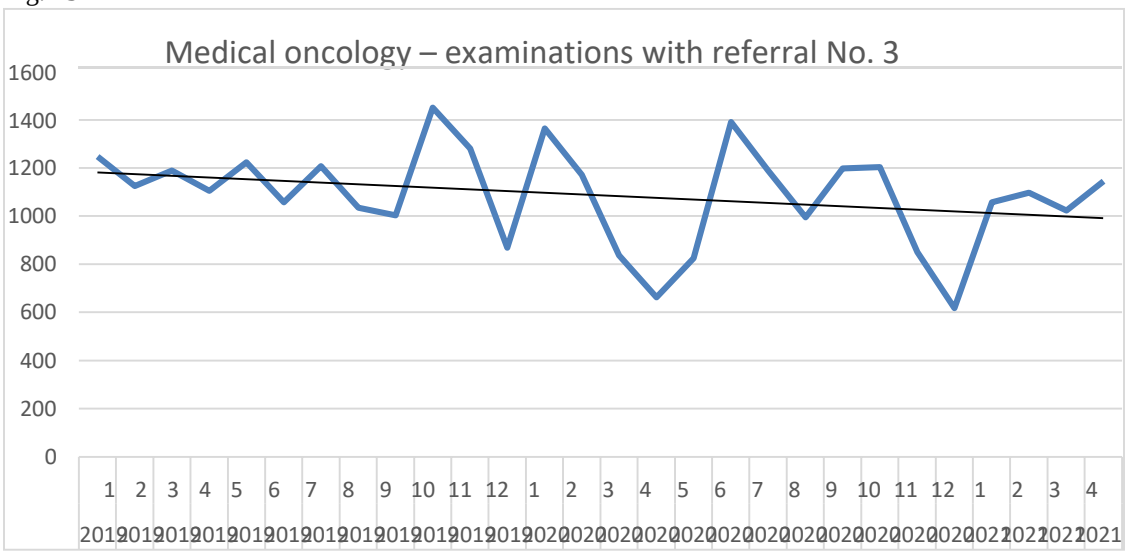


Source: NHIF

******** *In the annual report on the activities of the NHIF for 2019, published on the website of the Health Insurance Fund, it is reflected that the number of patients dispensed for respiratory diseases in 2019 is 204,381.*

For oncological diseases, the data from the NHIF[8] relate only to consultations performed in outpatient conditions. There is a dynamic situation with the number of examinations in 2020 and early 2021, with oncologists performing the fewest examinations in April and December 2020. (Figure 43)

Fig. 43



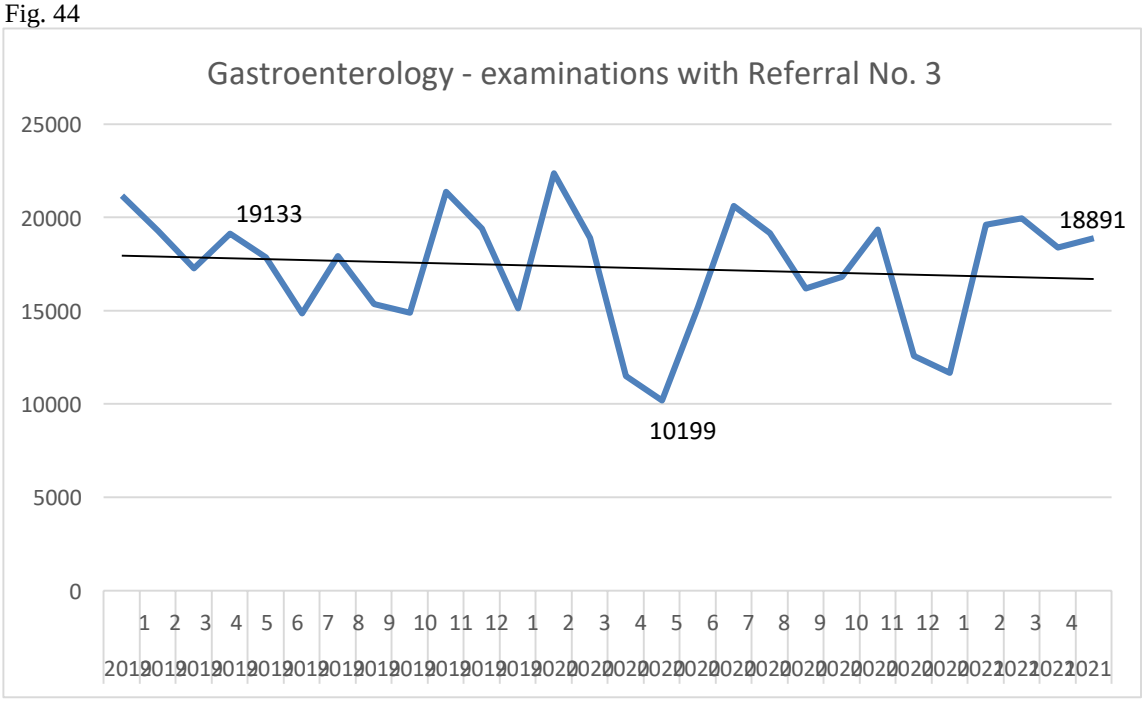
Source: NHIF

8 The NHIF did not provide data on oncological cases.

For 2019, the fourth most severe group of diseases causing deaths is *class XI diseases of the digestive system (K00-K93)*[9]. Therefore, data on the performance of gastroenterology specialists for the period January 2019-May 2021 are reviewed.

Figure 44 shows the number of outpatient gastroenterology consultations conducted. Again, it can be seen that for the months of March and April, gastroenterology consultations have halved compared to the same period in 2019. The work to track and conduct gastroenterology consultations compared to the circulatory and endocrine diseases described above has a similar trend.

Fig. 44

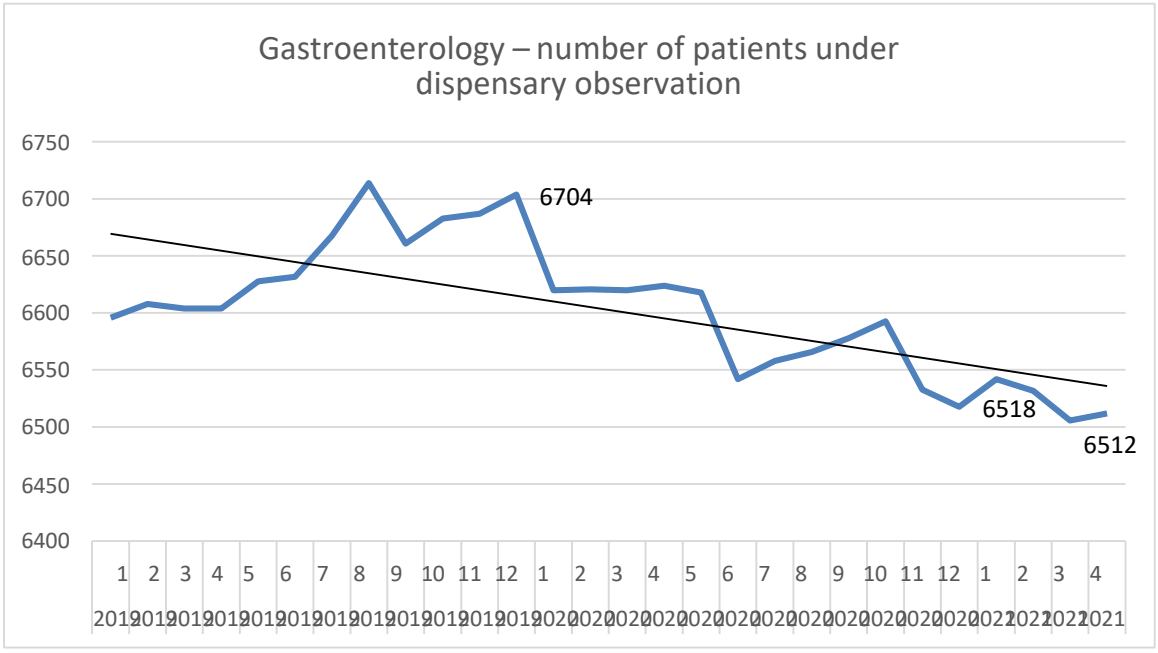


Source: NHIF

Regarding the dispensary patients for this class of diseases, there is again a downward trend in their number for the period January 2020-April 2021. Figure 45 shows the dynamics of this decrease.

9 NSI data for 2019:
https://www.nsi.bg/bg/content/3351/%D1%83%D0%BC%D0%B8%D1%80%D0%B0%D0%BD%D0%B8%D1%8F-%D0%BF%D0%BE-%D0%BF%D1%80%D0%B8%D1%87%D0%B8%D0%BD%D0%B8-%D0%B7%D0%B0-%D1%81%D0%BC%D1%8A%D1%80%D1%82%D1%82%D0%B0-%D0%BF%D0%BE-%D0%BF%D0%BE%D0%BB-%D0%B8-%D0%B2%D1%8A%D0%B7%D1%80%D0%B0%D1%81%D1%82%D0%BE%D0%B2%D0%B8-%D0%B3%D1%80%D1%83%D0%BF%D0%B8

Fig. 45



Source: NHIF

Analysis of data on diagnosis and treatment in home conditions of patients with COVID-19 from specialized outpatient medical care[10]

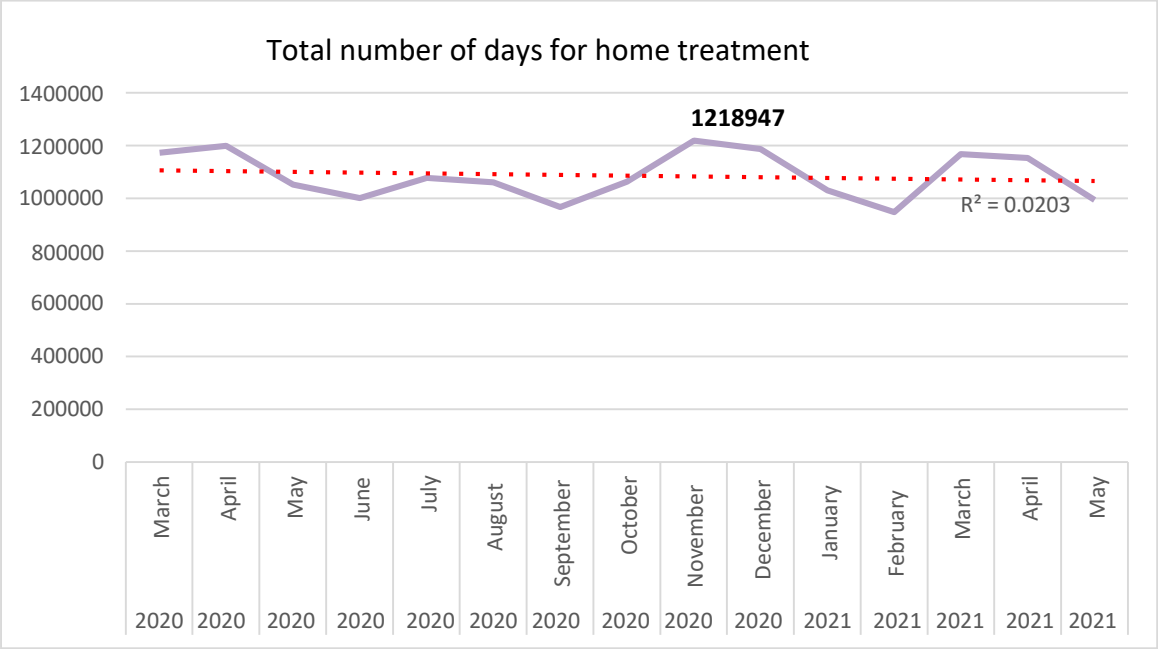
For the purposes of the analysis, the following information was requested from the National Social Security Institute:

- Total number of all sick notes and number of days for home treatment issued by SOMC for the study period;
- Number of sick notes of COVID-19-infected people and number of days for home treatment issued by a specialist under ICD-10 code (*U07.1 COVID-19, identified virus*);
- Number of sick notes of quarantined COVID-19 contacts and number of days in quarantine issued by a specialist under ICD-10 code U07.2 (*U07.2 COVID-19, unidentified COVID-19 virus*).

Figure 46 shows the total number of sick notes issued by SOMC for the period March 2020-May 2021.

10 Data from the NSI on the number of issued sick leaves and the number of days with temporary work disability.

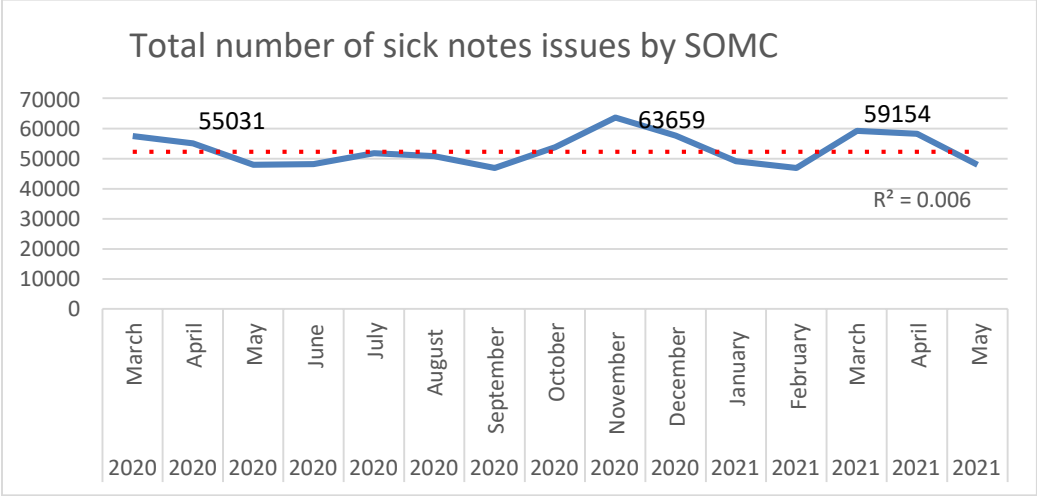
Fig. 46



Source: NSI

Figure 47 presents the total number of sick leaves issued from the start of the pandemic to April 2021. It is important to highlight that the number of sick leaves is a relatively constant quantity, in contrast to the number of days with work disability assessed by SOMC.

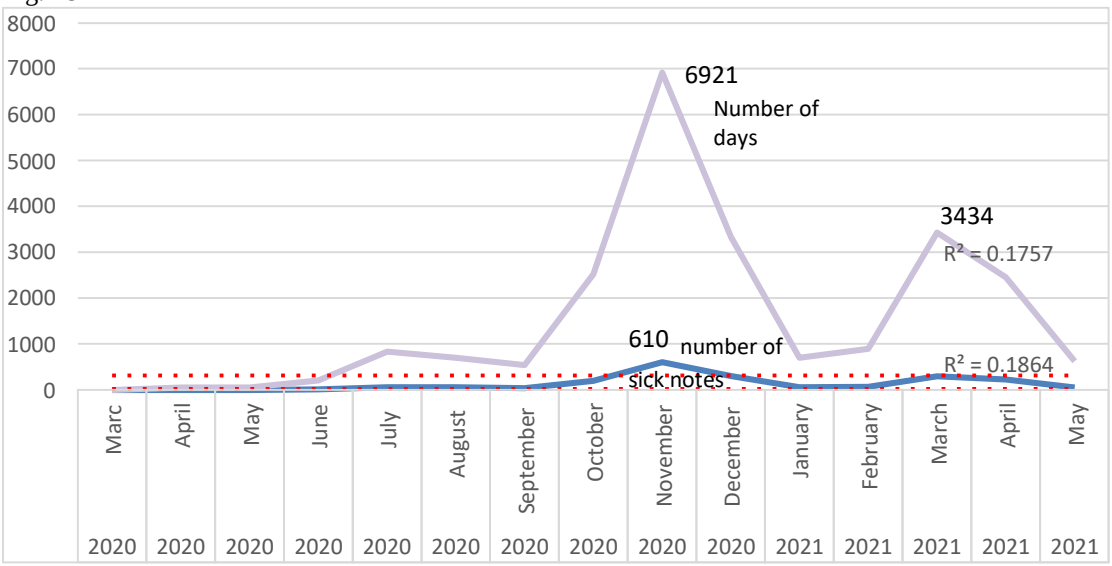
Fig. 47



Source: NSI

Figure 48 shows the dynamics of issuing sick notes to persons infected with coronavirus, as well as their days of temporary work disability.

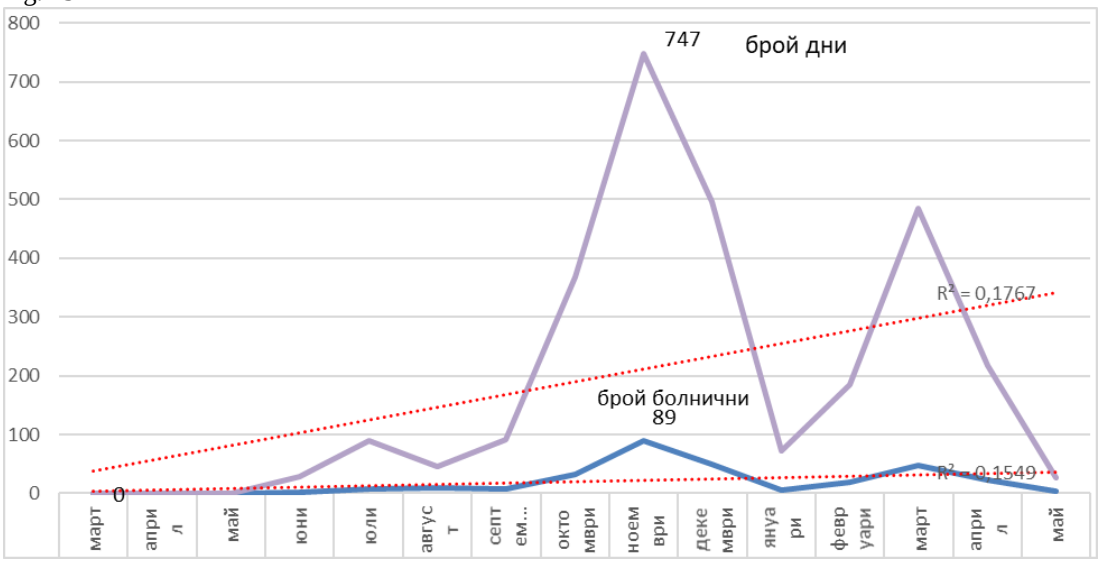
Fig. 48



Source: NSI

Similar data are shown in Figure 49, which presents the sick leave notes and the days of persons quarantined.

Fig. 49



Source: NSI

It is evident from the reported data that in terms of home treatment and follow-up, as well as the isolation of contact persons, outpatient care professionals have a relatively low activity in relation to coronavirus positive patients.

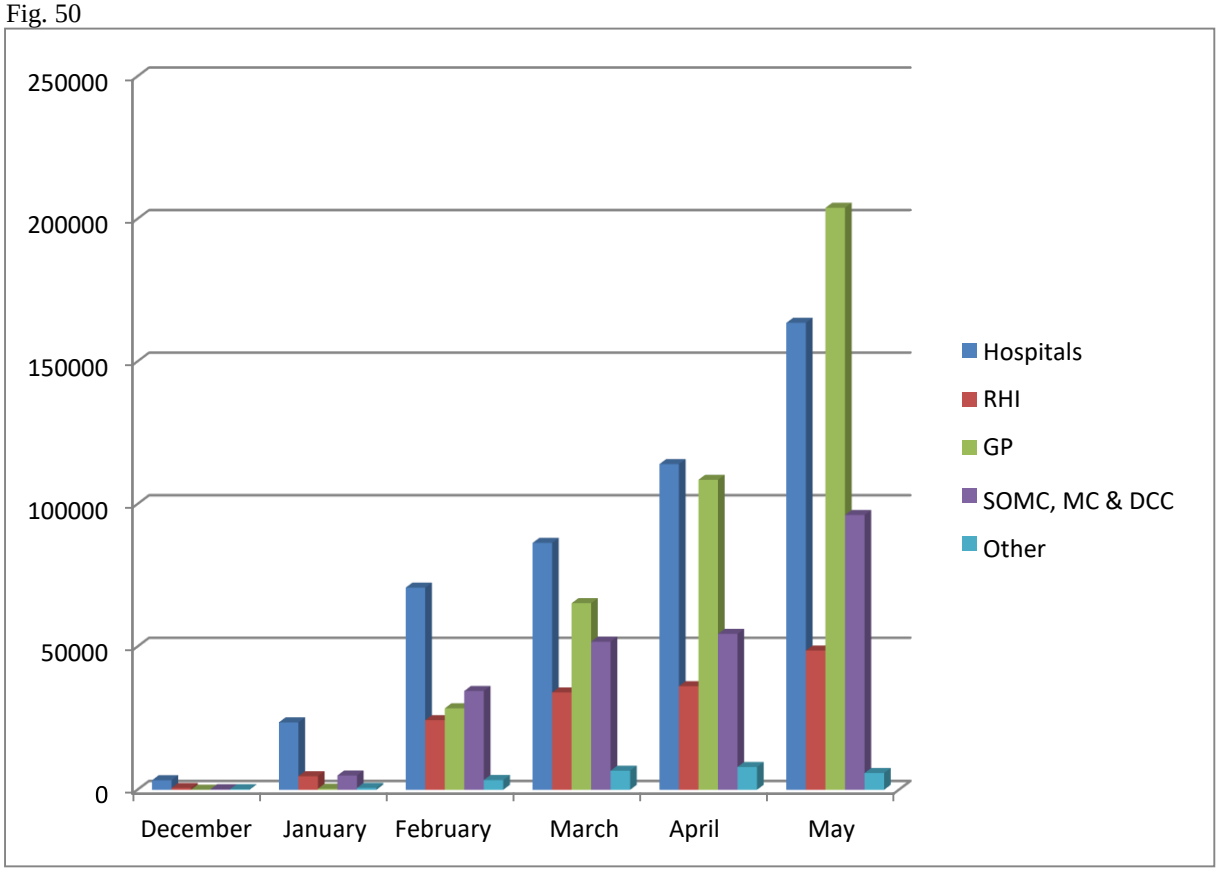
The trend of all hospital discharges from SOMC and the number of days recommended for home treatment remained almost constant from the start of the pandemic until the end of the study period in May 2021.

Analysis of administered vaccines by SOMC by scheduled regions in absolute terms and per 100,000 population[11]

The vaccination process in the country began in December 2020 with the delivery of the first EU approved vaccines. The following graphs show the vaccination activity of SOMC in comparison to hospitals, RHI's, GP's and other locations designated for vaccination by the government.

Figure 50 shows the total number of vaccines administered (in absolute numbers) in the country. The increased activity of specialists in May 2021 compared to previous months is evident.

Fig. 50

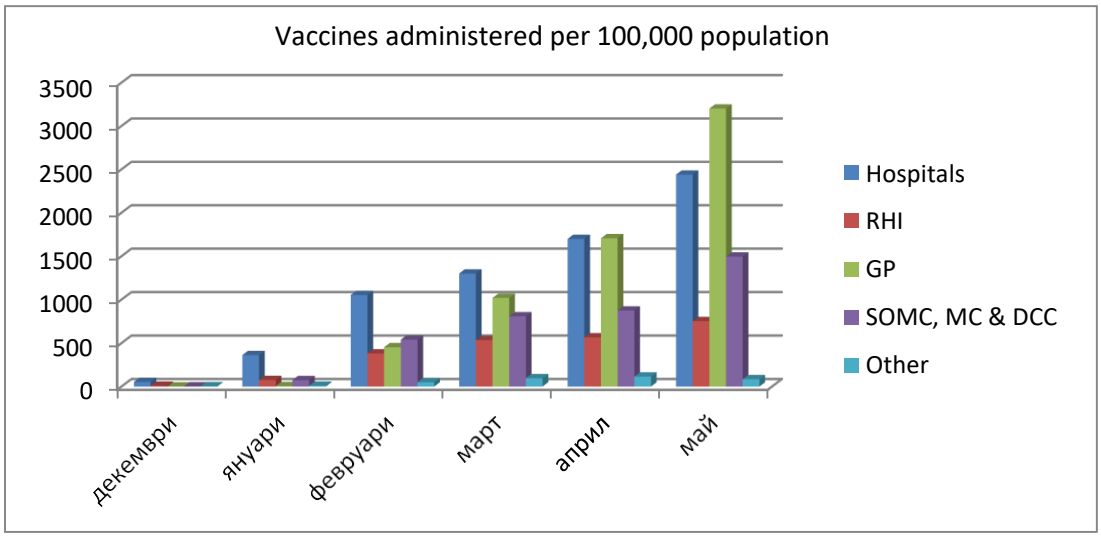


Source: RHI

Calculated per 100,000 population, the increasing role of GP's and SOMC in Bulgaria in the vaccination process is again evident, compared to the work of RHI's and other locations (beyond the so-called "green corridors" in hospitals). The figures are presented in Figure 51.

11 Data provided by RHI.

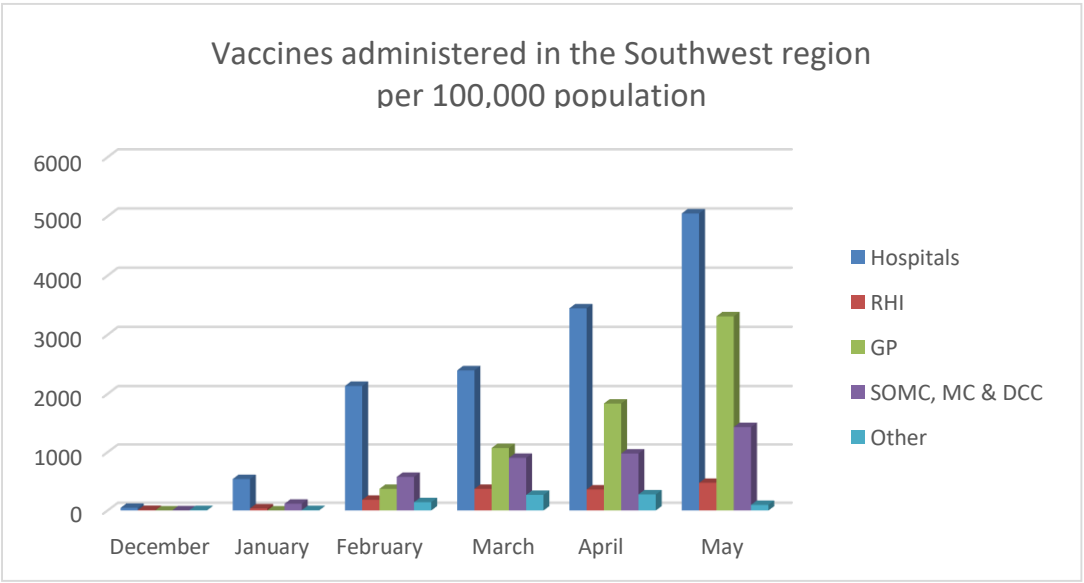
Fig. 51



Source: RHI

When the data provided to NCPHA by the RHI are recalculated per 100,000 population and examined at the level of scheduled regions in Bulgaria, it becomes clear that the vaccinations are mainly an activity of GP's and SOMC. The only exception is the South-West scheduled region (including Sofia-city and Sofia-region), where hospitals are the leading vaccination centres. (Figure 52)

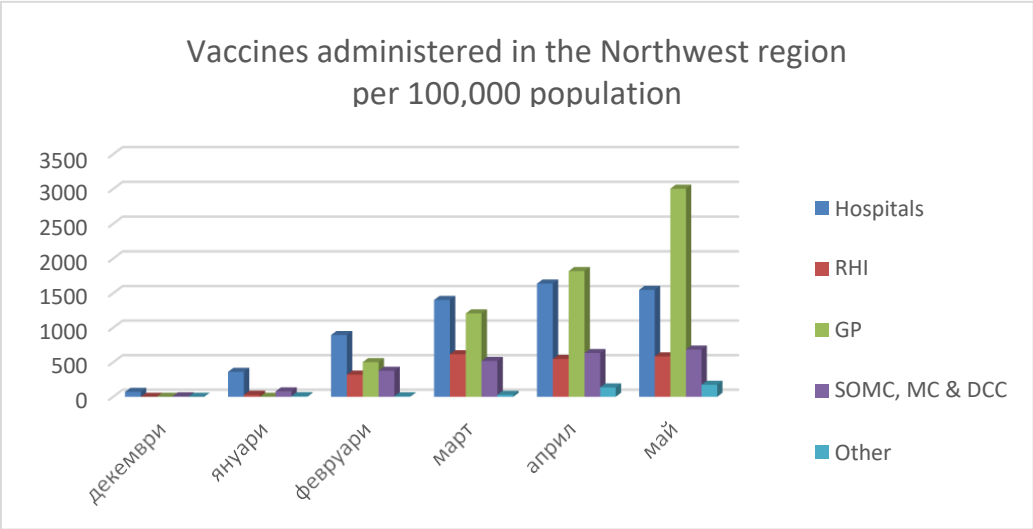
Fig. 52



Source, RHI

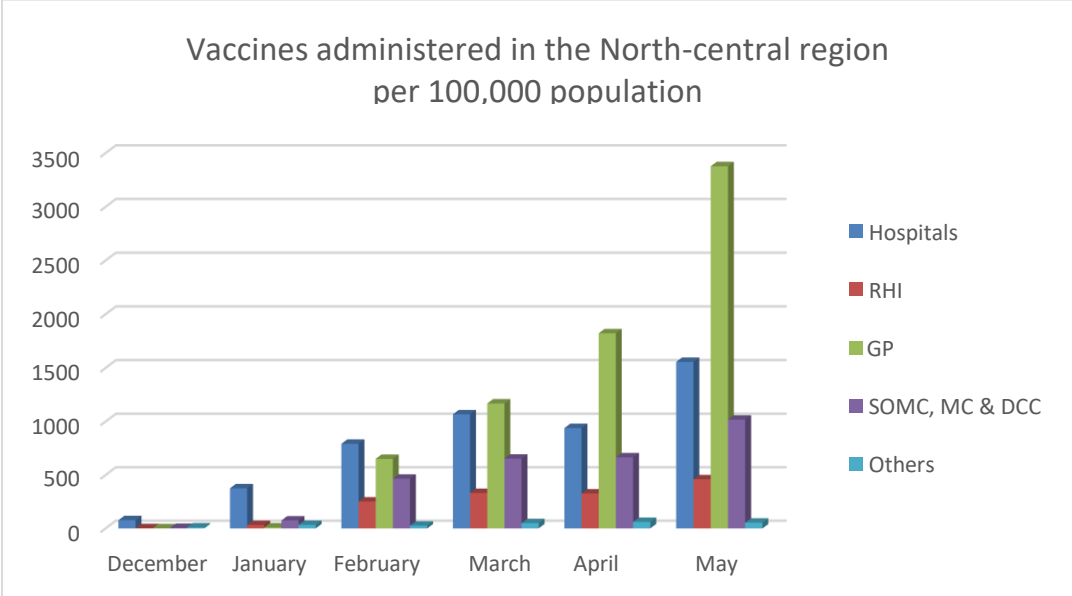
To further illustrate the above statements, the next five graphs present the vaccination activity by region.

Fig. 53



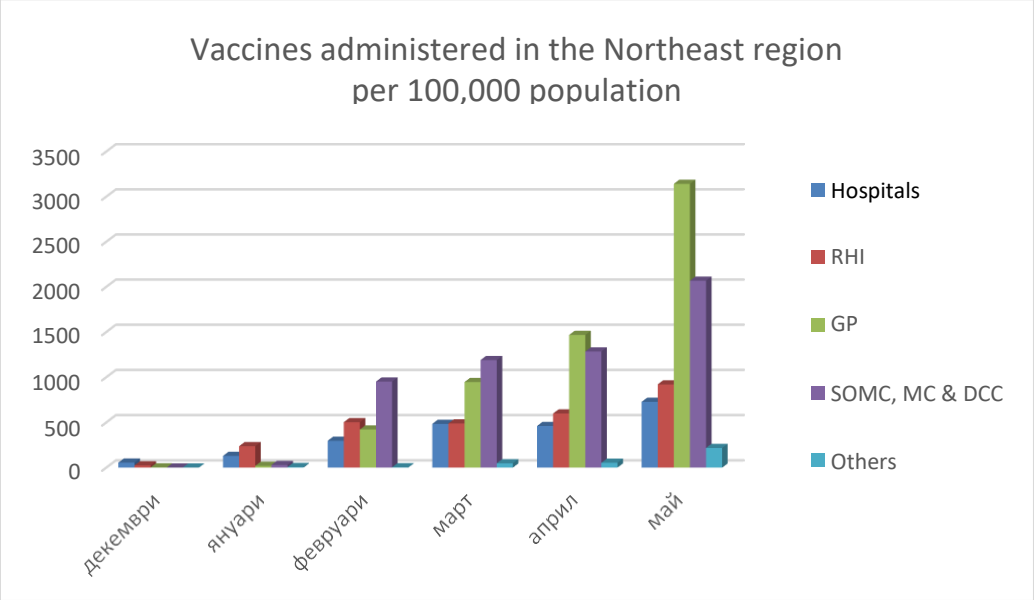
Source: RHI

Fig. 54



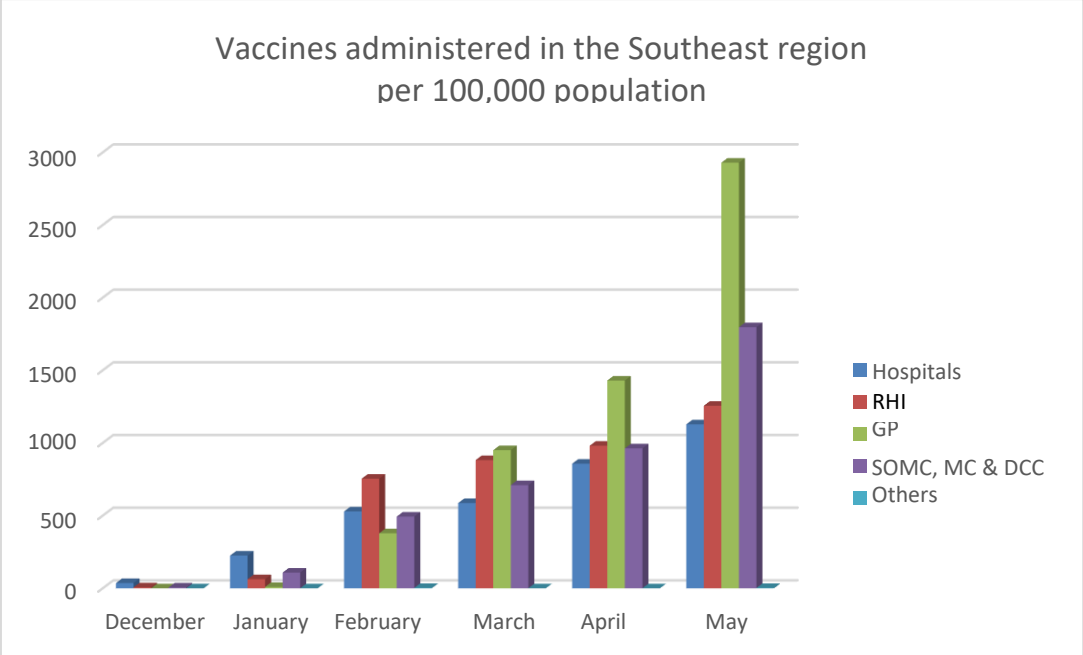
Source: RHI

Fig. 55



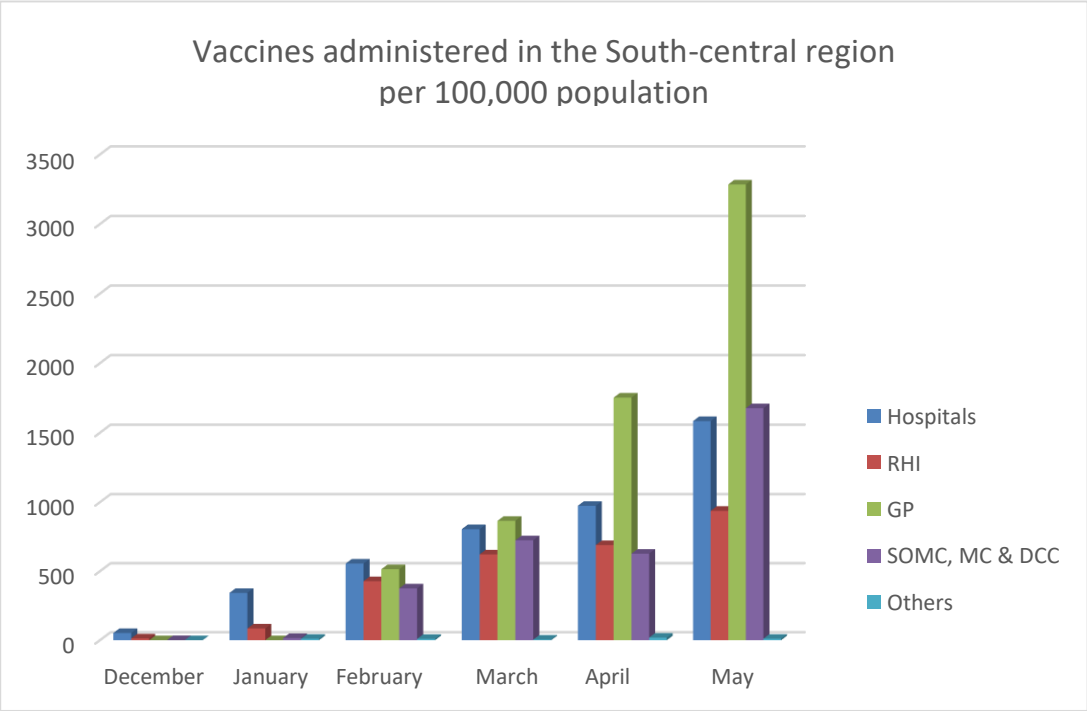
Source: RHI

Fig. 56



Source: RHI

Fig. 57



Source: RHI

Findings

The main findings of the analysis of the performance of the SOMC in the first year of the pandemic and for the period January to May 2021 are that there are two periods of reduced activity. The first period is March-April 2020, and the second is November-December 2020. There is a dramatic reduction in the number of people dispensed for the four main groups of chronic non-communicable diseases (circulatory, respiratory, endocrine and digestive).[12] It can be concluded that there is a steady downward trend in the number of persons under dispensary surveillance for cardiovascular, endocrine, pulmonary and neurological diseases. The most likely reason for dropping out of the dispensary for the socially important diseases listed is due to decease of the patients under dispensary.

Another important finding related to the vaccinations is that the involvement of large hospitals with the so-called "green corridors" does not lead to an increase in the motivation to vaccinate. The main role in the vaccination process outside the South-West region (including Sofia-city and Sofia-region) is mainly due to GP's, specialists in their individual practices, as well as medical centres and diagnostic-consultative centres.

12 There are no data from the NHIF on the dynamics in the number of patients with oncological diseases.

Part 5

Analysis of the activities of laboratories across the country

This review aims to summarize and analyse the types of diagnostic tests for SARS-CoV-2, the chronology of the establishment of a network of laboratories in Bulgaria, the strategies for conducting laboratory tests and the criteria that should be met by the tests and laboratories used, as well as imaging studies of the patients with COVID-19 in Bulgaria for the period March 2020-May 2021. The review is based on the Order RD 01-381/28.05.2021 (section 5) of the Minister of Health on the preparation of an analysis by the NCPHA of the activities related to the healthcare of the population in the context of the pandemic caused by SARS-CoV-2 and is based on national, European and global official regulatory and guidance documents, guidelines and strategies.

Setting of the study
In compliance with section 5 of Order RD-01-381/28.05.2021 of the Minister of Health, the following information has been requested from the RHI for each health facility/laboratory, for each district, broken down by month for the period March 2020-May 2021 and by age groups 0-18; 19-60; 60+:

1. Total number of tests (PCR and antigen) performed for the detection of SARS- CoV-2, out of which the number of positive results:

    - number of PCR tests performed; of these – number of positive results;
    - number of antigen tests performed; of these – number of positive results.

2. Number of quantitative tests for antibodies against SARS-CoV-2.

3. Total number of imaging studies (radiographic and CT-scans) of patients with COVID-19:

    - number of radiographic examinations;
    - number of CT-scans.

An excel spreadsheet was prepared and sent to all 28 district RHI's to be filled in. In order to avoid the duplication of information, a clarification was made to indicate in the columns only the number of tests performed by the laboratories inside and outside the health facilities within the district, i.e., if a sample was collected in a laboratory in the district for testing for evidence of SARS-Cov-2 and/or antibodies and it was sent for analysis to a laboratory outside the district, this sample is not included in the count.

By letters No. 1135/02.06.2021 and No. 1240/09.06.2021 to the Director of the NCPHA, a request was made to the MoH to provide us with data and access to data from the Unified Information Portal for COVID-19 on the tests performed by types for the evidence of SARS-CoV-2 in the period March 2020 to May 2021. We did not receive a response, therefore the analysis of the activities of the medical diagnostic laboratories for COVID-19 is based on the data received from the RHI.

The huge amount of information that had to be collected and completed delayed the submission of the data by the RHI. In the majority of the reports there were inaccuracies and incompleteness:

- there is no breakdown of the tests performed by type;
- the number of positive tests of each type is not recorded;
- the tests are not broken down by age group;
- a discrepancy between the number of tests performed and the number of positive tests;
- not all healthcare facilities have provided data to the RHI;
- 17 of the laboratories included in the orders of the Minister of Health have not provided results (shown in the list below with their serial numbers from Order RD 01-387/31.05.21):

  13. Medical-Diagnostic Laboratory CIBALAB EOOD, Sofia;

  18. Specialized Hospital for Active Treatment in Obstetrics and Gynaecology - Maichin Dom EAD, Sofia;

  21. Genetic and Medical-Diagnostic Laboratory GENIKA Ltd, Sofia;

  74. Independent medical-diagnostic laboratory "K-LAB" EOOD, Sofia;

  75. Medical and Dental Centre - Crystal AD, Sofia;

  78. Specialized Hospital for Active Treatment in Gynaecology and Assisted Reproduction "Dr. Malinov" Ltd, Sofia;

  92. Independent medical diagnostic laboratory VIRULAB EOOD, Sofia;

  98. Multi-profile hospital for active treatment - Byala Slatina EOOD, Byala Slatina;

  104. Cardiological Medical Centre EOOD, Pleven;

  105. DABOLAB - Independent Medical-Diagnostic Laboratory Ltd, Sofia;

  107. University Multiprofile Hospital for Active Treatment "MEDIKA RUSE" Ltd, Ruse;

  110. Medical Diagnostic Laboratory Botevgrad Ltd.;

  111. Independent Medical-Diagnostic Laboratory - Carilab-Excellence EOOD, Sofia;

  113. Medical diagnostic laboratory MED-DIA EOOD, Sofia;

  117. SANA - Independent Medical and Diagnostic Laboratory EOOD, Sofia;

  118. Medical Centre LASER MED Ltd, Sofia;

  119. Independent medical diagnostic laboratory KANDILAROV Ltd, Sofia.

Further information has been requested on the noted gaps. Where corrections and additions could not be made, apparently erroneous data were eliminated and not included in the treatment; in the absence of separation of surveys by species and age groups, information is included only in the totals.

Types of laboratory diagnostic tests to detect SARS-CoV-2

In general, the tests that are applied to detect SARS-CoV-2 can be grouped by scientific basis, type of technology, target users and location of testing. In terms of scientific basis, the tests available today for COVID-19 fall into two general categories: tests that detect the SARS-CoV-2 virus (tests with nucleic acid NAAT's), and tests that detect prior exposure to the virus (specifically the immune system response to the infection), in other words immunological tests. Not the least are the approaches to whole genome sequencing (WGS) with the aim of identifying the virus variants.

In the first category there are two subtypes: tests that detect the genetic material of the virus (by reverse transcriptase polymerase chain reaction—RT-qPCR) and on the basis of an

immunochromatographic method, and other tests that detect components of the virus, such as proteins on its surface (antigen tests). These tests are usually performed with nasal or throat samples (e.g., swabs or lavages) in cases where there is a risk of contact with a person with proven coronavirus infection 4 to 6 days after contact or when clinical symptoms appear 2 to 3 days after onset.

For the diagnosis of COVID-19, the WHO and ECDC currently recommend testing with RT-qPCR, a method that uses a polymerase chain reaction to amplify RNA. The method is the clinical gold standard for the etiological diagnosis of COVID-19, in which viral RNA is detected directly in respiratory samples with molecular biology tools and techniques (Habli et al., 2021). RNA is a single-stranded molecule and must be converted to a DNA sequence before it can be amplified. Obtaining a new DNA string that is complementary (matching) to the SARS-CoV-2 viral RNA is achieved by using an appropriate primer and the enzyme reverse transcriptase. The primer binds to the single-stranded RNA and the reverse transcriptase enzyme copies the RNA strand to produce single-stranded DNA, which is then copied to produce a double-stranded DNA molecule. The double-stranded molecule can now be amplified by PCR. Although RT-PCR is the gold standard with high specificity (~100%), sensitivity and accuracy, the procedure is labour-intensive and relies on sophisticated instrumentation, usually located in central laboratories, and requires the use of biosafety level 2 laminar boxes.

The tests to detect exposure to the virus are usually tests that detect antibodies produced in the blood by the patient's body in response to infection with the virus. These tests are also called serological tests because they are usually performed on a blood serum. For example, ELISA is a method of testing in the diagnosis of SARS-CoV-2 for the presence of IgA, IgM and IgG antibodies. With this laboratory method, the antigen (target macromolecule) is immobilized on a solid surface (microplate) and then complexed with an antibody that is bound to a reporter enzyme. Detection is performed by measuring the activity of the reporter enzyme by incubation with the appropriate substrate to yield a measurable product. The most important element of ELISA is a highly specific antibody-antigen interaction.

The early IgA and IgM antibodies start to form around day 3-5 of infection, peaking on day 10-14. This is when they are most likely to be evidenced by serological methods. This class of antibodies is retained for about 1.5-2 months. They are an indicator of an early, acute, active phase or of recovery after infection. Testing them dynamically helps to determine the immune response to an already confirmed positive result. Asymptomatic cases account for approximately 80% of all those infected but disseminating the virus.

The late IgG antibodies build up around day 14, increase and peak around day 25, and remain for a longer interval.

The detection of SARS-CoV-2 IgG facilitates the confirmation of the COVID-19 infection in patients with specific symptoms as well as asymptomatic cases (the majority of infected patients). Their testing is suitable for monitoring an infection that has already passed, especially when it comes to monitoring the immune response of collectives, clusters and other distinct groups.

For the reliability of the serological result, it is recommended to test both IgA and IgM antibodies, and IgG, as well as two patient samples—one from the acute phase on days 7-14, and one from the post-acute phase from 3 to 4 weeks later.

A wide variety of antibody tests against SARS-CoV-2 are available on the market. In attempts to diagnose COVID-19 early, antibody tests have been found to be poorly effective because antibodies can only be detected in the patient's blood days after infection. This depends, on the one hand, on each person's immune system and, on the other hand, on the sensitivity of the technique used. In addition, the antibodies remain for some time after the passage of the infection. They do not provide unequivocal evidence of the presence or absence of SARS-CoV-2 and therefore do not help to determine whether the person tested is a carrier. However, antibody testing can be extremely important in large-scale population-based seroepidemiological studies, for example in assessing the immune status of the population, and is a significant factor in determining strategies for phasing out containment measures once the pandemic is contained.

Each method used in commercial testing should be validated. To ensure validity and metrological traceability of both the methods and the results, on 1 April 2020 the first certified reference was produced at the Joint Research Centre (JRC) of the European Commission—EURM-019 Single-stranded RNA (ssRNA) fragments from SARS-CoV-2, a synthetic non-virulent RNA fragment. The reference material makes it possible to harmonise coronavirus tests, thus ensuring high quality and validity of results and avoiding false negative results.

The SARS-CoV-2 virus is changing rapidly. This means that today there are different variants of SARS-CoV-2 viruses. The control material designed by the JRC scientists is based on the part of the virus that has remained stable after mutation. This means that the control material is fully compatible with the official WHO-recommended methods used in the EU, Asia and the USA for detecting the presence of SARS-CoV-2.

The material can also be used to compare and validate the numerous test suites currently being developed worldwide. Today, the reference material is available to testing laboratories throughout the EU, including major virology reference centres as well as hospitals. The samples are highly concentrated. In practice, only a very small amount of material is required to verify a test. This means that one sample is sufficient for one laboratory to verify up to 20,000 tests.[13] In late 2020, a verification was performed of the JRC validated reference material for the detection of the new variant then found in the UK.[14] Three certified reference materials are currently available: EURM-017, EURM-018 (two new quality control reference materials for SARS-CoV-2 antibody tests) and EURM-019 (single-stranded RNA (ssRNA) fragments from SARS-CoV-2, a synthetic non-virulent RNA fragment).

Chronology of the establishment of a network of laboratories in Bulgaria

The laboratory diagnosis of SARS-Cov-2 in Bulgaria started in February 2020 and is initially carried out in two laboratories: The National Reference Laboratory for 'Influenza and Acute Respiratory Infections' at the NCIPD and the Virology Laboratory at the Military Medical Academy. Both laboratories are accredited according to BDS EN ISO/IEC 17025:2018.

On 13 March 2020, the Government, together with the National Coronavirus Task Force, proposed the introduction of exceptional counter-epidemic measures in the country until 13 April, with the

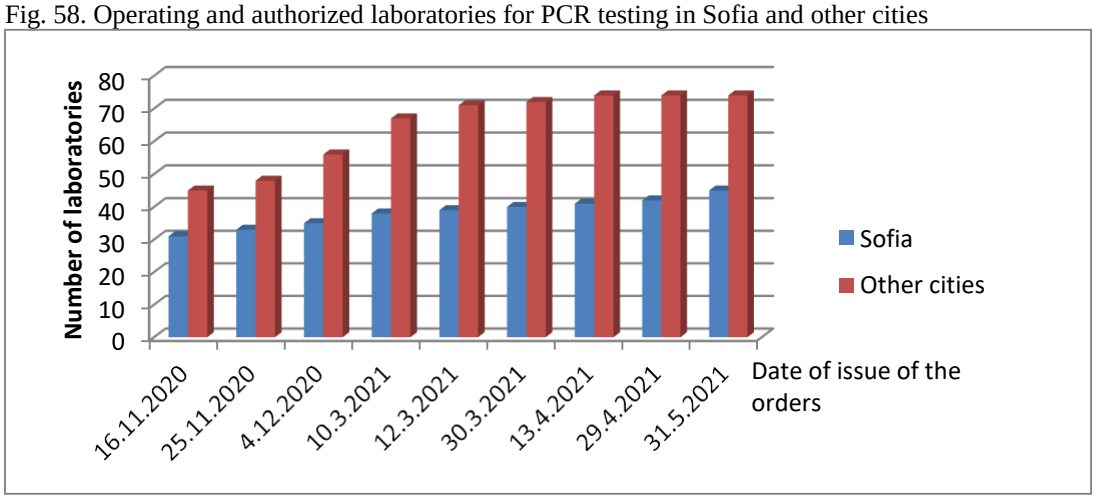
[13] https://ec.europa.eu/jrc/en/news/new-control-material-developed-jrc-scientists-help-prevent-coronavirus-test-failures

[14] https://ec.europa.eu/jrc/en/news/verification-validity-jrc-reference-material-quality-control-detection-recent-variant-covid-found-uk

Parliament unanimously approving this measure (Order No. RD-01-124/13.03.2020). Very soon after, other laboratories started to analyse samples, as they are trained and supported by the National Reference Laboratory (NRL) to the NCIPD.

At the end of March 2020, in accordance with the order of the Minister of Health RD-01-150-25.03.2020, in Annex 3 of the order, 5 medical and health facilities were designated for conducting laboratory tests for the confirmation of COVID-19, of which two are located in Sofia and the other three in Varna, Stara Zagora and Burgas. Fifteen days later, according to another order RD-01-193-10.04.2020, the list was supplemented by two more laboratories in Plovdiv and hence bringing the total number of laboratories to 7. At the end of April 2020, the name of Annex No 3 of order RD-01-245-30.04.2020 was changed to 'Medical and health establishments for carrying out highly specialised medical and diagnostic testing "Polymerase chain reaction for confirmation of COVID-19"'. Four new laboratories were opened in Sofia, bringing the total number of laboratories to 22 (15 in Sofia, 7 in other cities). One month later (May 2020), the number of COVID-19 authorized institutions increased steadily to 31 (17 in Sofia, 14 in other cities). In accordance with a new order RD-01-284-29.05.2020, regional health inspectorates for conducting the highly specialised medical-diagnostic test 'Polymerase Chain Reaction for the demonstration of COVID-19' are included in Annex 3. It can be noted that within only two months (from March to May 2020) the number of authorized medical establishments increased six-fold: from 5 to 31 (17 in Sofia, 14 in other cities). In the period June-October 2020, the total number doubles from 32 to 65 (26 in Sofia, 39 in other cities). In November 2020, the laboratory capacity was further increased to 81 laboratories. In the following seven months (until the end of May 2021), the number of laboratories for PCR testing is 118, with a significant increase in the number of laboratories throughout the country (73) and exceeding that in the capital (45).

Fig. 58. Operating and authorized laboratories for PCR testing in Sofia and other cities



Source: MoH

Officially, rapid antigen tests are included in the statistics of the Unified Information Portal for COVID-19 by Order No. RD-01-724/22.12.2020 of Minister Kostadin Angelov. The same order also regulates the analytical principles for confirming suspicious results by carrying out repeated arbitration analyses of suspicious samples in the NRL for "Influenza and Acute Respiratory Diseases" at the NCIPD. According to the above-mentioned order, point 7 states: "The first five positive and the first ten negative results of the highly specialised medical-diagnostic test 'Polymerase chain reaction for the detection of COVID-19' carried out in the laboratories after their inclusion in Annex 3, shall be sent for confirmation by the National Reference Laboratory

'Influenza and Acute Respiratory Diseases' of the National Centre for Infectious and Parasitic Diseases." In Annex 3 of the same order, the "Medical, health facilities and regional health inspectorates for conducting highly specialized medical diagnostic testing 'Polymerase chain reaction for the demonstration of COVID-19'" are specified. In order to ensure the validity of the results, this procedure should be carried out prior to inclusion of the laboratories in the list in Annex 3. The text in point 8 is justifiably and in accordance with the good laboratory practices: "All suspicious/inconclusive results of the highly specialised medical diagnostic test 'Polymerase chain reaction for the detection of COVID-19' that are carried out in the laboratories under point 7 are sent for confirmation by the National Reference Laboratory 'Influenza and Acute Respiratory Diseases' of the National Centre for Infectious Diseases and Parasitic Diseases." As an NRL at the NCIPD maintains a management system in accordance with BDS EN ISO/IEC 17025, it provides methodological support and training to all laboratories performing diagnostics of SARS-CoV-2 and ensures external control through inter-laboratory comparative trials.

In line with the 'Guidelines on diagnostic tests for COVID-19 and their characteristics' (2020/C122 I/01) of 15 April 2020, a network of reference laboratories for COVID-19 across the EU, as well as a platform to support them, is to be established in the closest collaboration between Members States and following consultation with the ECDC. The activities will include facilitation of information exchange, identification of laboratory needs, management and distribution of control samples, external quality assessment, method development, organisation and follow-up of comparative testing, and exchange of knowledge and skills. The Commission will coordinate the work of the network and provide Member States with the necessary analytical support in managing the crisis and mitigating its consequences.

Strategies for performing laboratory tests

During March 2020, the WHO, ECDC and the EC prepare recommendations for a laboratory testing strategy for COVID-19, leaving each country to make decisions at national level according to the specificities of the country situation.

According to data from The Health System Response Monitor (HSRM) – Monitoring the health system response[15] in Bulgaria, as in all EU countries, the criteria for mandatory testing change over time. In Bulgaria, initially, travellers arriving from high-risk countries with symptoms of acute respiratory diseases were tested, after which the National Operational Staff decided to also test patients with a viral infection hospitalised in infectious disease units. After diagnosing the first cases on 8 March 2020, the scope of testing is revised to include suspected cases and close contacts are from then on also tested. On 10 April 2020, the number of PCR tests performed reached 18,502 or more than 2,640 per 1 million population. According to official data, at the beginning of November 2020, the number of PCR tests performed increases to over 10,000 per day and the total number of PCR tests exceeds 120,000 per 1 million population. However, in terms of RT-PCR testing, Bulgaria still lags behind many European countries.

The criteria which the used tests and laboratories should meet

As of the beginning of April 2020, the medical devices for testing for COVID-19—marked with "CE" under Directive 98/79/EC 1 of the European Parliament and of the Council of 27 October 1998 concerning *in vitro* diagnostic medical devices—are approximately the following in number:

[15] https://www.covid19healthsystem.org/countries/bulgaria/countrypage.aspx

78 devices for RT-PCR tests, 13 for rapid antigen detection tests, 101 for antibody detection tests, most of which are rapid. To date, they are considerably more and exceed 1000 in each category. At present, ready-made analytical tests meeting the criteria under Directive 98/79/EC are being used in Bulgaria.

The laboratories listed in Annex 3 are approved by the Ministry of Health in accordance with Ordinance No. 35 of 6 August 2010 on the approval of the medical standard 'Clinical laboratory', by providing proof of the organisation of activities, personnel, technical means and methods. In view of the specific nature of the COVID-19 diagnostic tests, each laboratory should have the status of a diagnostic laboratory for virological tests and meet specific requirements relating to the organisation of work in virological and molecular genetic laboratories and, ideally, be accredited in accordance with the conditions laid down in standards ISO IEC 17025 (testing laboratories) or ISO 15189 (medical laboratories), as well as have appropriate premises, technical facilities, biosafety level 2 laminar boxes and qualified personnel. The accreditation is a voluntary act and is not legally required.

The verification of the validity of methods and results is performed with certified reference materials and by participating in interlaboratory reference comparisons and suitability tests.

Performed medical-diagnostic tests in Bulgaria for proving SARS-CoV-2, tests for antibodies against SARS-CoV-2, imaging examinations of patients with COVID-19 for the period March 2020 - 31 May 2021

The information on the conducted medical-diagnostic tests for COVID-19 in Bulgaria for the period March 2020-May 2021, obtained from the 28 RHI's, is summarized and presented in figures and tables.

A total of 426 laboratories operated in the country: 110 of them performed RT-qPCR tests, 325 – antigen tests, 136 – quantitative antibody tests, 404 – imaging of patients with COVID-19 (266 radiographic, 138 CT examinations). The largest number of laboratories by region during this period was in Sofia-city – 86, and in descending order followed by Plovdiv – 35, Varna – 28, Pleven and Stara Zagora – 23, Veliko Tarnovo – 18. The smallest number of laboratories operated in the districts Vidin (3) and Targovishte (4).

The total number of all tests performed by the laboratories inside and outside the health facilities for the period was 3,763,483. Of these, 1,830,845 PCR tests, 831,631 antigen tests, 520,625 quantitative antibody tests, 580,382 imaging tests on patients with COVID-19 (518,037 radiographic, 62,345 CT scans). Sofia-city had the highest number of tests of all types. In terms of PCR examinations, after Sofia (1,022,232 pcs.) in descending order follow Burgas with 140,647 pieces and Plovdiv with 125,447 pieces. Laboratories in Sofia-region and Dobrich did not perform PCR tests (they were sent to Sofia and Varna, respectively). The total number of antigen tests performed was the highest in Sofia – 394,268, followed by Varna with 56,919 and Burgas – 44,058. Sofia-region did not provide information on the number of antigen tests performed. The number of quantitative antibody tests in Sofia was 314,886, in Burgas – 81,246, in Varna – 33,993; no such tests were performed in Sofia-region. Regarding imaging examinations of patients with COVID-19, the number of lung radiographs reported in Sofia was 100,020 and CT scans – 19,518; in Plovdiv – 20,948 and 6,464, respectively; in Blagoevgrad – 18,928 and 8,248, respectively. In Lovech district no imaging examinations of patients with COVID-19 were reported. There is no

data on CT scans in Vidin for the entire period.

In calculating the relative proportion of positive samples to the total number of tests performed in the survey period (in %), it was considered that until 21.12.2020 only PCR tests had any diagnostic value and until this date the percentage has been calculated as the ratio of the number of positive PCR samples to the total number of PCR tests performed. After this date, the results of antigen tests are also recognised and the relative proportion is given as the number of positive PCR and antigen tests to the total number of PCR and antigen tests performed. By district, the highest proportion of positive results from laboratories is in Lovech – 54.1%, followed by Sliven – 36.25% and Kyustendil – 32.9%; in most of the other districts it was within the range of 20-25%. For Sofia-region and Dobrich, the relative proportion of positive samples is 0%, as no PCR and antigen tests were performed in Sofia-region and antigen tests were performed in Dobrich at a time when their results were not considered informative.

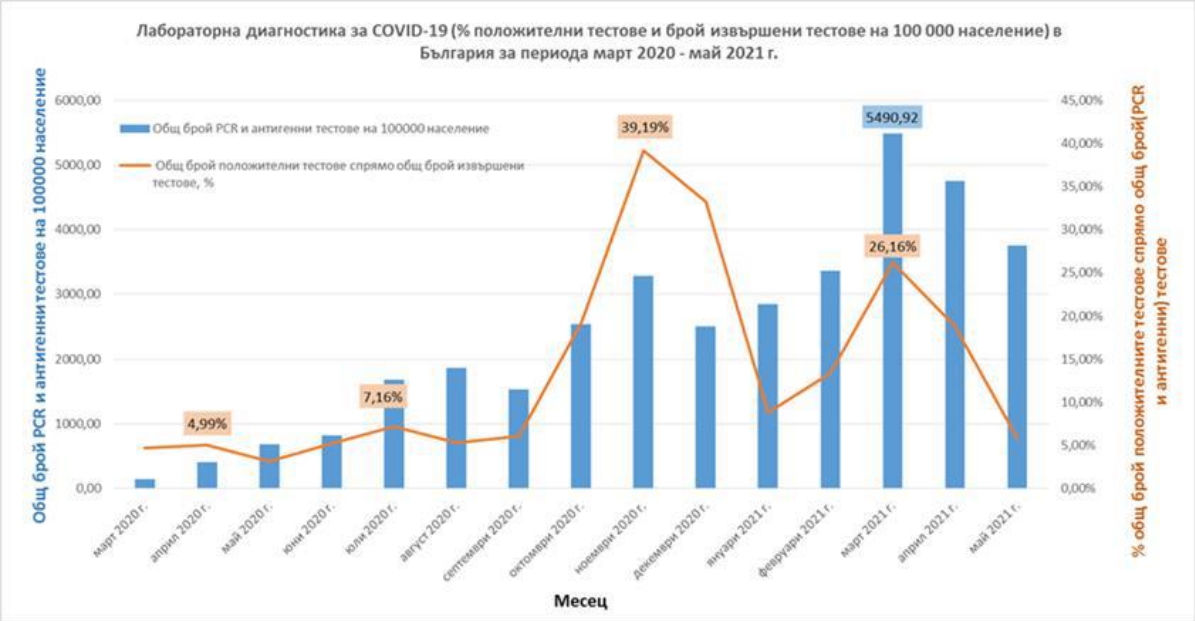
Based on the total number of positive COVID-19 test results performed in the laboratories of a given area, no calculations of population incidence could be made, since the results refer to the number of samples tested in the laboratories of the area, not to the number of persons tested by residence. The number of samples analysed in laboratories—besides from within the district—is supplemented by the number of samples sent from other districts where there are no laboratories carrying out this type of testing.

Laboratory tests for diagnosis of COVID-19 in Bulgaria by month for the period March 2020 - May 2021

At the beginning of the period (March-May), the number of COVID-19 laboratory tests performed in the country increase, mainly due to performed PCR tests. In July and August (13 June until the end of the lockdown), the total number of tests doubled compared to June, probably related both to the increase in the number of laboratories able to perform them and partly to the requirement for a negative PCR test when travelling abroad during the summer holidays. In confirmation of this, the relative proportion of positive tests remains at almost the same level.

Between October and January, the total number of tests conducted on a monthly basis reached 3,285/100,000 population. A steep increase started to be observed in the relative proportion of positive samples, reaching 39.2% on a monthly basis in November-December (first wave), confirming the increasing intensity of the epidemic process associated with COVID-19. (Figure 59)

Fig. 59: Laboratory diagnosis of COVID-19 (% positive tests and number of PCR and rapid antigen tests performed per 100 000 population)



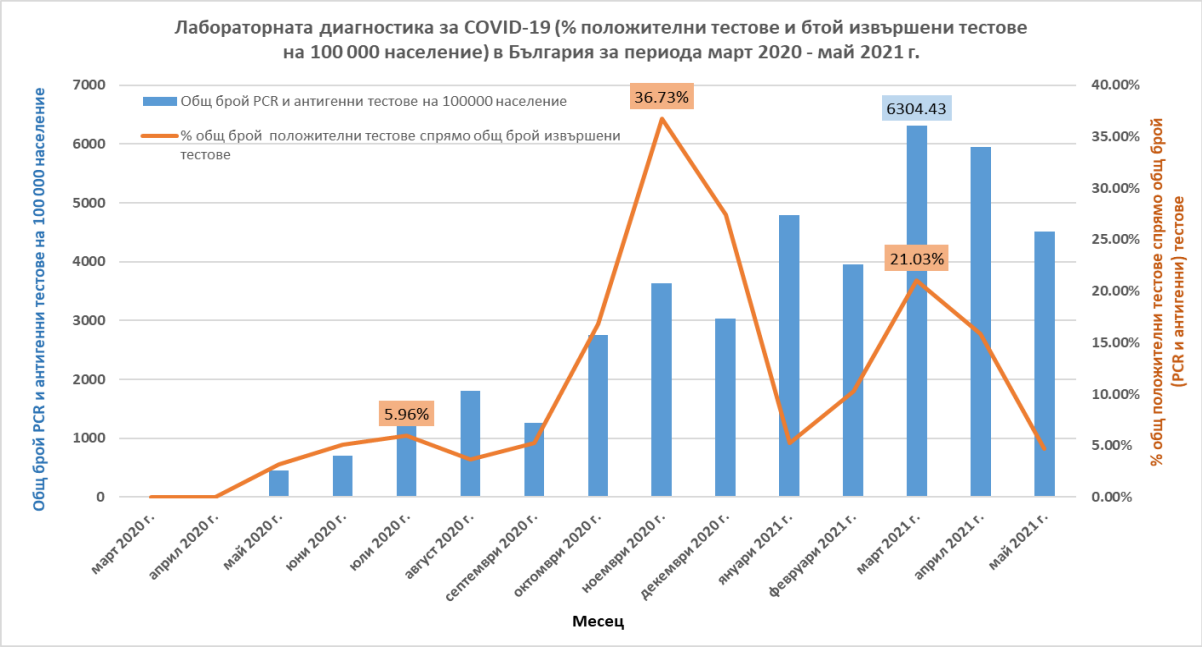
Source: RHI

In the following period, January-May, the number of tests performed continues to be high (reaching 5,500 per 100,000 population in March), indicating that the population is informed and aware of the importance of the disease and the responsibility towards relatives, and therefore, when symptoms of COVID-19 are present, tests are performed to prove it. The percentage of positive tests also increases after January (when students start attending school), reaching a peak (26.2%) in March and dropping slightly in April (the second wave March-April, clearly outlined in the graph), and by May it is already down to September levels. In the second wave, the relative proportion of positive samples for COVID-19 was about 1.5 times lower than in the first wave, reflecting the impact of the vaccination of at-risk populations that started in January.

The increase in the number of laboratories competent and designated to perform specialised tests for the detection of SARS-CoV-2 is also relevant to the growing number of tests. During the 'surge' periods, the number of tests performed would probably have been even higher if it had not been for the high cost of PCR testing. Unlike other European countries where testing is completely free (e.g. France – completely free, Austria – twice weekly an antigen test, Germany – one antigen test per person per day), in Bulgaria it is paid by the patient. It would be good, including in terms of pandemic management, if in the future this type of testing were covered by the Health Insurance Fund or the state budget.

Figure 60, with data manually extracted from the COVID-19 Portal, shows by month the changes in the number of specialized tests to detect COVID-19 per 100,000 population, as well as the relative proportion of positive samples. These follow the same pattern as the curves in the previous Figure 59.

Fig. 60. Laboratory diagnosis of COVID-19 (% positive tests in relation to total number of tests performed and number of PCR and rapid antigen tests performed per 100,000 population)



Source: Unified Information Portal for COVID-19

According to the data submitted to the RHI, the quantification of antibodies by the laboratories started in March 2020 – 987 tests were performed when the pandemic was just beginning in Bulgaria; in April they increased tenfold to 9,244. The highest number of antibody tests was reported in March – 85,328 and April – 83,016. In this period, vaccination is already underway and many of those who have been vaccinated or vaccinated have performed these tests informatively.

Regarding imaging studies (lung radiographs and CT scans) of patients with COVID-19, data analysis is difficult. Already at the beginning of the pandemic in March 2020, the total number of tests was 16,690, compared to a total of 10,556 PCR and rapid antigen tests for the diagnosis of SARS-CoV-2. The reported data are incorrect, as it is very likely that most facilities report the total number of imaging tests performed in a given month without any link to the COVID-19 diagnosis. At the same time, the large increases in November (84,834) and December (80,785), as well as in March (83,050) and April (77,552), are probably also related to the disease. According to a publication by authors from Wuhan (Tao Ai et al., 2019), chest CT has a high sensitivity for the diagnosis of coronavirus disease (COVID-19) and can be considered as a tool to detect COVID-19 in epidemic areas as well as to establish the cure rate. Early in the pandemic, image-based diagnostics may have been used to diagnose patients with symptoms in areas where SARS-CoV-2 testing laboratories were not yet available.

Distribution by age groups

The distribution by age group of tests performed for COVID-19 shows that the sum of the number of tests by age group does not correspond to the total number of tests due to some laboratories not providing such a distribution.

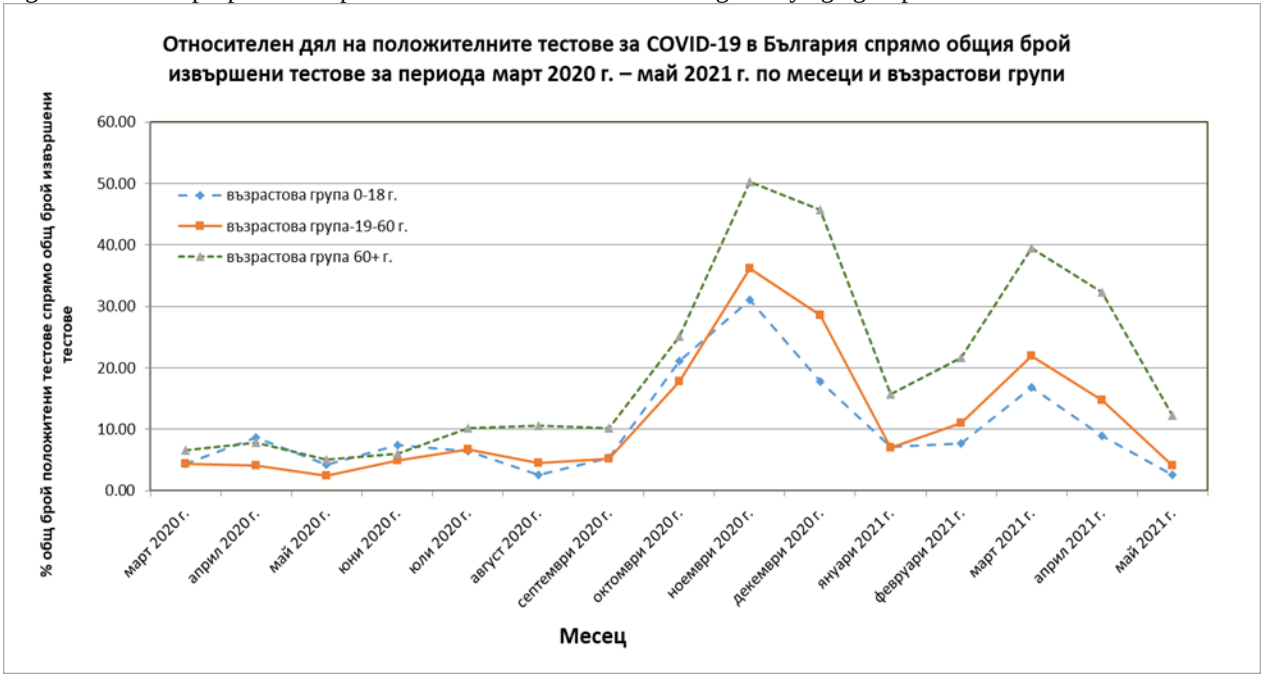
Given the widespread prevalence of COVID-19 throughout the country, positive results of the

applied diagnostic tests for COVID-19 are reported in all ages. Their relative proportion is highest in the group of elderly people aged 60 years and over—on average for the period it was 27.7%, followed by the group aged 19-60 years with 14.9% and the lowest in children aged 0-18 years – 10.3%.

During the period March-September 2020, the percentage of positive samples is in the range of 2.5-10% for all age groups. From October, a sharp rise begins—the first wave—with a peak in November, most pronounced in the 60+ group, with 50.2% of results positive, 45% in December. The course of the curves for the other two age groups follows the same trend.

After a decline in the relative proportion of positive tests towards the end of the year, the start of attendance at school in February saw a renewed increase in the number of confirmed cases among children. This increase is also seen in the 19-60 and 60+ age groups. The peak is reached in March 2021 at 16.77% in the 0-18 age group, 21.91% in the 19-60 age group, with the highest relative proportion of positive tests in the 60+ age group at 39.5% (second wave March-April 2021). (Figure 61)

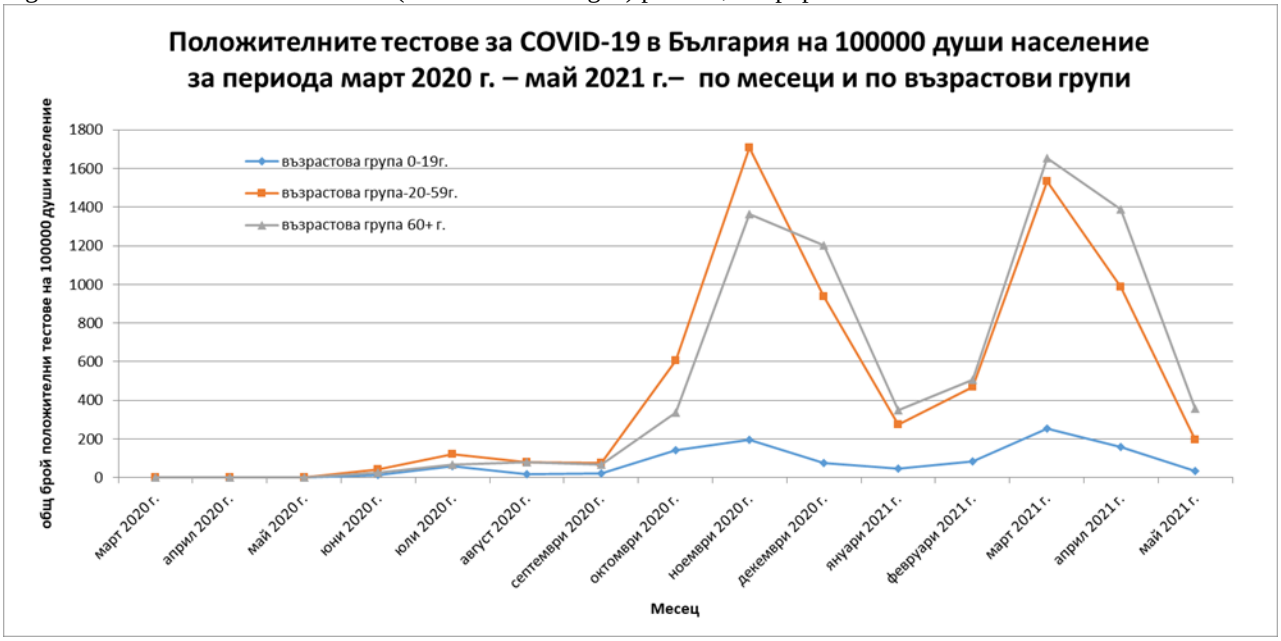
Fig. 61. Relative proportion of positive tests for COVID-19 in Bulgaria by age group



Source: RHI

Figure 62, based on data extracted from the COVID-19 Information Portal, shows the changes in incidence (number of positive tests per 100,000 population) for the period March 2020-May 2021 by age group.

Fig. 62 Positive tests for COVID-19 (RT PCR and antigen) per 100,000 population



Source: Unified Information Portal for COVID-19

At the peak intensity of the first wave of the epidemic in November 2020, the highest number of positive samples per 100,000 population was in the 20-59 age group – 1707, followed by the 60+ age group – 363, children 0-19 – 197. It is noteworthy that at the peak of the second epidemic wave, the incidence in children 0-19 years and in persons over 60 years increased compared to the first wave by 12-13%.

Laboratories performing COVID-19 diagnostic tests in Bulgaria for the period March 2020 - May 2021

Figure 63 shows the growth in the number of laboratories from March 2020 to May 2021. By orders of the Minister of Health, hospitals, health facilities and RHI's have been designated to carry out highly specialised medical diagnostic testing 'Polymerase chain reaction for the demonstration of COVID-19'. At the end of March there were 5 laboratories, and with the last order they reached 118 (in the list of Annex 3 to Order RD 01-387/31.05.21 there are 119 laboratories, but No. 41 and No. 44 are the same laboratory – Medical Centre EXAKTA MEDICA Ltd., Pleven).

The total number of all laboratories performing PCR and antigen testing for SARS-CoV-2, antibody testing and imaging of COVID-19 patients was 130 at the beginning of the period and reached 426 at the end.

Fig. 63. Number of laboratories performing specialized medical-diagnostic activities to detect COVID-19

Source: Unified Information Portal for COVID-19

The detailed database (in Excel) with information on the activities of all laboratories, hospitals, health facilities and RHI's performing medical diagnostic tests for COVID-19—for each health facility, for each district and in aggregated form for the country, broken down by month for the period March 2020 - May 2021 and by age groups 0-18 years, 19-60 years and 60+ years—is available at the National Centre for Public Health and Analysis (NCPHA).

Findings

Bulgaria has a sufficient number of diagnostic laboratories equipped with the necessary technical means (equipment) and expert capacity to perform both diagnostic tests with nucleic acid amplification (RT-qPCR) and immunological tests to detect antigens and antibodies to SARS-CoV-2. However, in terms of RT-qPCR testing, Bulgaria still lags behind many European countries.

The NRL on 'Influenza and Acute Respiratory Diseases' at the National Centre for Influenza and Respiratory Diseases provides methodological support and training to all laboratories performing SARS-CoV-2 diagnostics, as well as external control through interlaboratory comparative tests.

In Bulgaria, diagnostic tests are applied in accordance with Directive 98/79/EC of the European Parliament regarding *in vitro* diagnostic medical devices.

Attention should be paid to internal laboratory control and ensuring metrological (using certified reference materials) traceability of results to ensure the validity of results.

Antibody testing can be particularly informative in large-scale seroepidemiological studies of populations to assess their immune status. The information obtained is of great importance for the development of strategies and decision-making for the gradual lifting of restrictive measures once the pandemic has been contained.

The laboratory diagnostic tests performed in the country for COVID-19 from March 2020 to May 2021 reflect the trend in the epidemic situation. The increase in their total number, as well as the relative proportion of positive samples, corresponds and defines very clearly the two waves of the pandemic.

The specialized examinations reveal the development and intensity of the epidemic process associated with COVID-19 in all age groups, including children, but particularly pronounced in the elderly.

The high cost of RT-qPCR testing affects the total number of tests. Unlike other European countries (e.g. France – completely free, Austria – twice weekly antigen test, Germany – one antigen test per person per day), where testing is free of charge, in Bulgaria it is paid by the patient.

Part 6

Analysis of the activities of hospital care

Hospital care as part of the health care system in Bulgaria was not prepared for the COVID-19 pandemic. The pandemic revealed weaknesses in the hospital care system that have been known for years but which have now re-emerged. Hospital beds—their number, structure and territorial distribution—are indicators of the availability of and access to hospital care. According to the NSI and the NCPHA, as of 31.12.2019, the number of hospital beds was 51,776 and the provision per 10,000 people with hospital beds was 74.5. As of 31.12.2020, the number of hospital beds is 51,991 and the insurance coverage per 10,000 people is 75.2. The better coverage rate is the result of population reduction and not of targeted action by health authorities.

As of 31.12.2020, there are 184 multi-disciplinary hospitals with 38,256 beds, which means that 57.2% of the hospitals have 73.6% of the country's bed stock. The number of beds varies widely from 23 to 1540. The largest share is in the multiprofile hospitals, which at the end of the year had between 100 and 299 beds – 41.0%. Up to 99 beds were available in 37.2% of the multiprofile hospitals. 8.2% of this type of hospitals have more than 500 beds.

As of 31.12.2020 there are 137 specialised hospitals with 13,735 beds. Their breakdown by type is as follows:

- for active treatment – 74 with 4,415 beds;
- for long-term treatment – one with 145 beds;
- for long-term treatment and rehabilitation – 16 with 1,978 beds;
- for rehabilitation – 34 with 5,083 beds;
- State psychiatric hospitals – 12 with 2,114 beds.

In accordance with the methodological requirements and the harmonised definitions with regard to the hospital care facilities, these also include centres with an inpatient unit. At the end of 2020 these are:

- centres for skin and venereal diseases – 3 facilities with 30 beds;
- complex oncology centres – 7 with 1,185 beds;
- mental health centres – 12 with 1,010 beds.

The provision of hospital beds to the population at the end of 2020 is 783.9 per 100,000 of the population and increases by 7.1 points compared to 2019 (776.8). The highest values of this indicator are in the districts of Smolyan (1040.4 per 100,000 population), Pleven (1015.3) and Plovdiv (1011.0), while the lowest are in the districts of Pernik (371.2), Yambol (388.0) and Vidin (412.5).

At the start of the pandemic, the Ministry of Health issued Order RD-01- 121/11.03.2020 ordering the RHI's to take measures to reorganize and increase the available bed stock to ensure admission and treatment of COVID-19 cases. Later, the MoH issued Order RD-01-159/27.03.2020, which describes in Annexes 1 to 4 the number of beds for treatment and observation of uncomplicated patients, the number of beds for intensive treatment of patients with COVID-19, as well as the recommended requirements for opening an infectious disease unit for admission of uncomplicated cases of COVID-19 and the recommended requirements for intensive treatment. The Order's recommended maximum number of newly opened beds for COVID-19 treatment are presented in Table 1.

Table.1 Number of beds for uncomplicated patients and beds for intensive care

District	Beds for treatment and observation of uncomplicated patients	Intensive care ICU beds
Blagoevgrad	280	53
Burgas	251	55
Varna	278	67
Veliko Tarnovo	286	24
Vidin	69	6
Vratsa	192	28
Gabrovo	155	13
Dobrich	133	11
Kardzhali	109	15
Kyustendil	234	24
Lovech	212	13
Montana	231	22
Pazardzhik	366	67
Pernik	129	10
Pleven	382	24
Plovdiv	725	178
Razgrad	106	16
Ruse	279	48
Silistra	115	14
Sliven	284	27
Smolyan	168	9
Sofia-city	1137	430
Sofia-region	333	26
Stara Zagora	281	56
Targovishte	147	22
Haskovo	218	38
Shumen	165	16
Yambol	126	12

Source: MoH

In implementation of the cited order and in preparation for dealing with the COVID-19 cases, hospitals began transforming beds, initially mainly in the infectious and internal medicine departments. At a later stage and in view of the complicated epidemic situation, hospitals were transforming beds from all available vacant wards.

Figure 64 shows the dynamics of bed openings for treatment and monitoring of uncomplicated cases with COVID-19. The trend of bed openings is clearly outlined, coinciding with the number of reported positive cases.

Fig. 64 Opening of COVID-19 beds for treatment and monitoring of uncomplicated patients

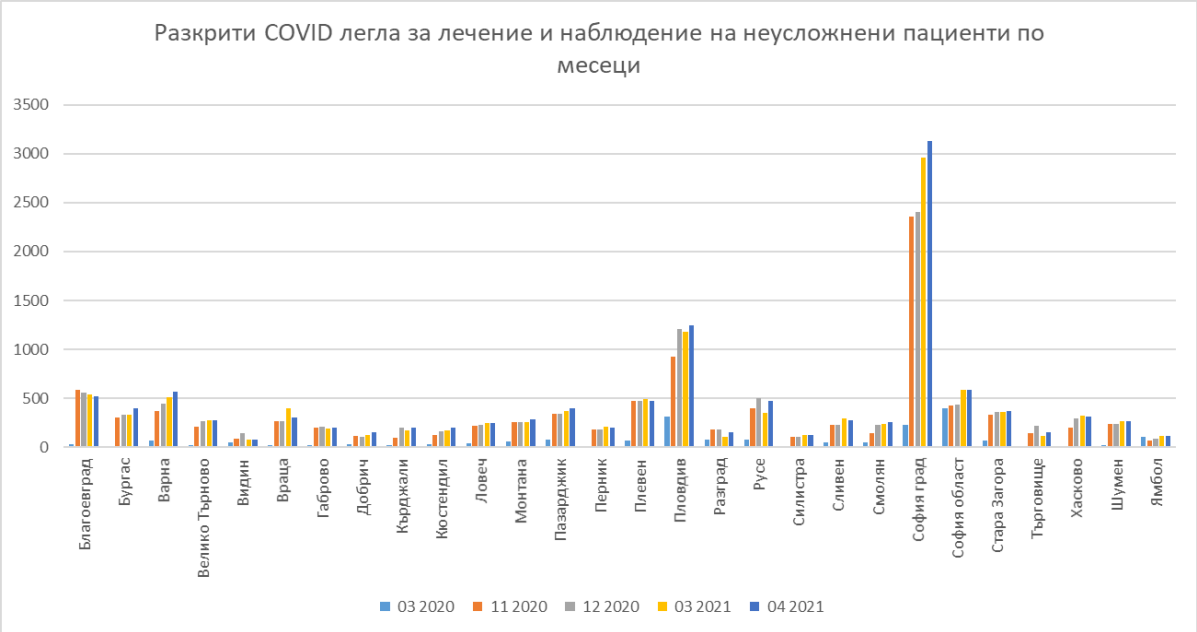
Source: RHI

One cannot ignore the fact that for the period March-September 2020, the number of beds for uncomplicated cases increased by only 770, while in one month—in the period October-November—the number increased by 5,454. The reasons for this increase can be sought in two directions: on the one hand, the escalating number of newly detected cases in the period of the so-called first wave, and on the other in the adopted annex to the National Framework Agreement 2020-2022, in which the cost of clinical pathways №39 and №48 for the treatment of COVID-19 from 01.11.2020 increased to BGN 1,200.

The transformation of beds for COVID-19 treatment naturally follows and replicates the uneven distribution of inpatient care facilities. Five months were analysed over the period March 2020-May 2021, namely: March 2020 – the beginning of the pandemic in Bulgaria and the first measures taken by the health authorities; November and December 2020 – the peak of the first wave of COVID-19; March and April 2021 – the peak of the second wave of COVID-19.

At the beginning of the period the highest number of beds for uncomplicated patients out of the total number of such beds was in Sofia-region – 20.1%, in Plovdiv – 15.9% and in Sofia-city – 11.5%. Correspondingly, the lowest number of beds was in Pernik – 0%, Silistra – 0.1% and Haskovo – 0.3%. During the peaks of the COVID-19 waves, the highest percentage of beds was in Sofia-city – 24.6% and 26.2% respectively for the second wave; in Plovdiv – 11.4% and 10.4%; in Blagoevgrad – 6.1% and 4.8%. In the same periods, beds in Yambol accounted for 0.8% and 1.0% of the structure of the analysed indicator; in Silistra– 1.1% and 1.1%; and in Vidin– 1.3% and 0.9%. Figure 65 presents the number of beds opened for the months selected for analysis.

Fig. 65 COVID-19 beds opened for treatment of uncomplicated patients



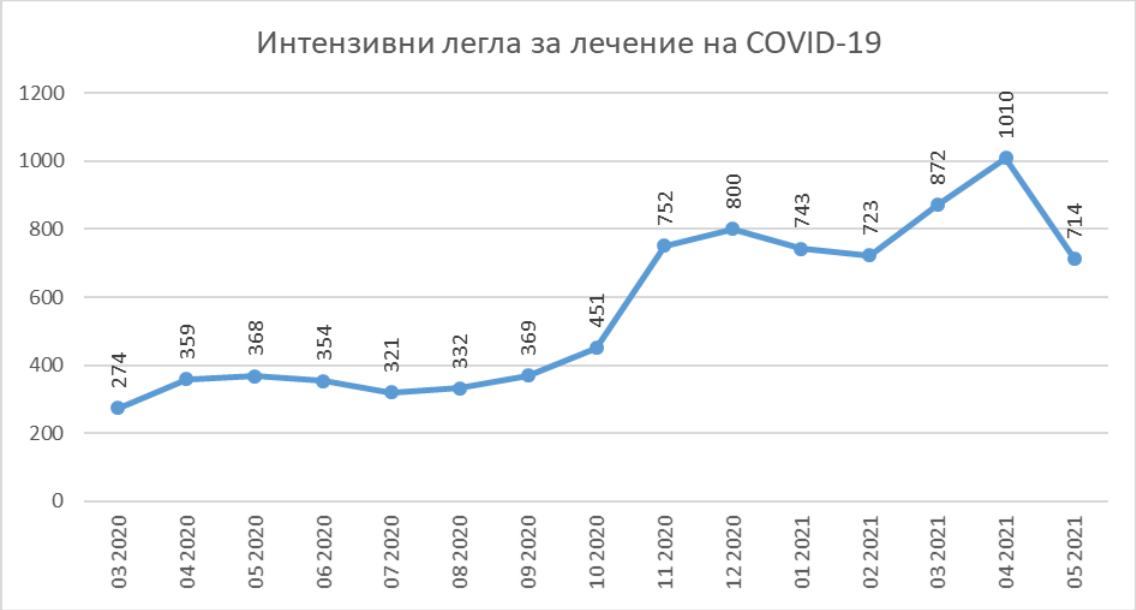
Source: RHI

The analysis of the structure of transformed beds for treatment and observation of uncomplicated patients shows that during the first wave in some districts the percentage of beds for COVID-19 treatment reached close to and over 40%, for example Pernik – 46.8%, Blagoevgrad – 42.6%, Lovech – 37.3%, whereas during the second wave in Pernik 55% of beds were for COVID-19 patients, in Smolyan – 45.7%, in Lovech – 40.8%. At the same time, in Pernik there is a deterioration of hospital lethality indicators—the highest in the country, leading in deaths caused by diseases of Class IX, Diseases of the circulatory organs and Class XI, Diseases of the digestive system, although it is unfounded to look for a direct link between transformed beds and deaths from these classes of diseases.

The data obtained from the RHI on the opening/transformation of intensive care beds for patients with COVID-19 shows that the curve is completely identical to the curve of bed transformation for uncomplicated patients, both of which follow the dynamics of the spread of infection—with a smooth increase at the beginning, and peaks in the first and second waves and declines after them.

Figure 66 shows the dynamics of transforming intensive care beds to treat patients with COVID-19.

Fig. 66 Dynamics of transformation of intensive care beds



Source: RHI

The provision of intensive care beds should comply with Annex 4 of Order RD-01-159/27.03.2020 and meet the relevant requirements for available equipment. With the data collected and in accordance with the given instructions, the present analysis cannot answer the question whether and to what extent the relevant instructions of the MoH have been complied with.

The number of hospitalizations in Bulgaria for 2020 is significantly lower than the same indicator for 2019. Overall, they are down by 621,786 despite COVID-19 hospitalizations, which in percentage terms represents a 25.8% decrease. Decreases were seen in all disease classes, but the most significant decreases were in Class IX, Diseases of the circulatory system – 91,990 fewer hospitalizations; Class X, Diseases of the respiratory system – 81,381 fewer hospitalizations; Class II, Neoplasms – 66,667 fewer hospitalizations; Class XI, Diseases of the digestive system – 47,467 fewer hospitalizations, etc. The structure of hospitalizations in 2020 remains similar to the structure in 2019. Figure 67 illustrates the structure of hospitalizations in the year without COVID-19 and the first year of the pandemic. It should be noted that patients hospitalized with COVID-19 in 2020 account for only 3% of the hospitalization structure.

Fig. 67 Structure of hospitalizations by year

Sources: NCPHA, NHIF

Another characteristic of hospitalizations and their change from early 2020 to the end of the analysis period (May 2021) is that hospitalization rates by month remain lower than those in February 2020, the last month without COVID-19 (Figure 68). An explanation could be sought in the transformation of hospital beds from the different clinics and wards into beds for the treatment of COVID-19 patients. Another possible explanation is the cessation of routine admissions to the hospital care facilities in implementation of the regulations for compliance with the anti-epidemic measures. There may also be psychological arguments for delaying hospital admissions, but these are beyond the scope of this analysis.

Fig. 68 Dynamics of hospitalizations January 2020 - May 2021

Source: NHIF

The hospitalizations diagnosed with COVID-19 begin in April 2020, although the first cases in Bulgaria were confirmed in March. This discrepancy is due to the fact that as of March, there is still no code to codify the cases, as this code is generated by the WHO in addition and extension of the ICD – 10th revision.

As can be observed in Figure 69, in the months of April-September the hospitalized cases fluctuated, but it can be argued that the trend is upward. These relatively few hospitalizations gave the health authorities six months to prepare and adapt the hospital system for the eventual (and expected!) increase in the number of proven cases, respectively hospitalizations. At the end of October, there were over 4,000 cases and these were a precursor to the first wave of COVID-19 infections—in the following two months, cases were in the order of 20,000-25,000. In January 2021, hospitalizations declined, a trend that persisted into February, but a second wave of infections occurred in March and April, mainly with the "Alpha" variant of COVID-19. Hospitalizations during these two months were in the range of 22,000-28,000. By the end of May 2020, the number of hospitalisations was below 12,000, and the trend is now downwards.

Fig. 69 Hospitalizations with COVID-19 by month

Source: NHIF

The average length of stay per admitted patient varied between disease classes, which is to be expected, with no seasonal variation or apparent bias occurring as a secondary effect due to those hospitalized with COVID-19. Those hospitalized for Class VII, Diseases of the eye and adnexa, had the shortest average stay – 0.9 days, and those hospitalized for Class XVI, Certain conditions occurring during the perinatal period, had the longest stay – 9.1 days. For the analysed period (March 2020 to May 2021), the average stay was 4.2 days, which was less than the average hospital stays in 2019 – 5 days.

The average length of stay of those hospitalized with COVID-19 should be analysed separately. The characteristic there is that in the initial months of infection the average stay was high, for example in May 2020, with 545 hospitalized, the average stay was 14.3 days, in June, with 492 hospitalized, the average stay was 12.8 days, and even before the first wave, with 1,710 hospitalized in October, the average stay was 12.3 days. In the months of the first wave, however, the average stay decreased to 8.5 days in November and 9.4 days in December. The same was observed during the second wave, with 8.6 and 9.2 days of average stay for the months of March and April 2021, respectively, and 10.8 days for the month of May immediately thereafter. When the mortality data is added, it is found that the reduction in average stay is rather a consequence of patients dying—deaths in the respective months are over 3,000 per month.

As of 31 December 2020, the population of Bulgaria is 6 916 548. Compared to 2019, the country's population decreases by 34 934 people. The number of deaths in 2020 is 124 735 and the total mortality rate is 18.0‰. Compared to the previous year, the number of deaths increased by 16,652. In 2020, there is an apparent decrease in hospital mortality compared to 2019, but without considering the new class of diseases, "Class XXII, Special Case Codes (COVID-19)". In 2020, 25,134 deaths were reported in hospitals, compared to 29,629 deaths in 2019. This represents a decrease in absolute terms of 4,495 and as a percentage the decrease is 15.2%. When the figures for those who died with a diagnosis of COVID-19 are added, the numbers change significantly. There were 7,674 deaths reported with a diagnosis of COVID-19 in hospital care settings in 2020. This makes 2020 a year with more deaths in hospitals compared to 2019. As an absolute number, hospital deaths in 2020 exceeded 2019 by 3,179 deaths, and as a percentage increased by 10.7%. It could be argued that the resulting numbers are entirely derived from COVID-19 diagnosed deaths in hospitals.

To summarize the information reported: fewer deaths in hospital facilities from the classes of diseases compared to 2019; with the addition of a new class for COVID-19 case reporting, hospital deaths in 2020 exceed 2019 deaths, but not on a scale to explain the overall increase in deaths. The It needs to be concluded that people died outside hospitals, most often in their homes. (Figure 70)

Fig. 70 Deaths by class of disease in hospital care facilities – 2019 and 2020

Source: NCPHA, NHIF

The analysis of deaths by cause over the analysis period showed that the four leading disease classes caused the deaths of 38,921 people, which was 80.1% of all those who died in hospital. These four classes were Class XXII 'Codes for Special Events (COVID-19)' – 18,114 deaths (37.3%), Class IX 'Diseases of the Circulatory System' – 12,224 deaths (25.2%), Class XI 'Diseases of the Digestive System' – 4,929 deaths (10.1%), and Class X 'Diseases of the Respiratory System' – 3,654 deaths (7.5%). Usually Class II 'Neoplasms' also has a large share in mortality, but this is true in the general statistics, not in the hospital statistics. The leading disease classes are presented in Figure 71.

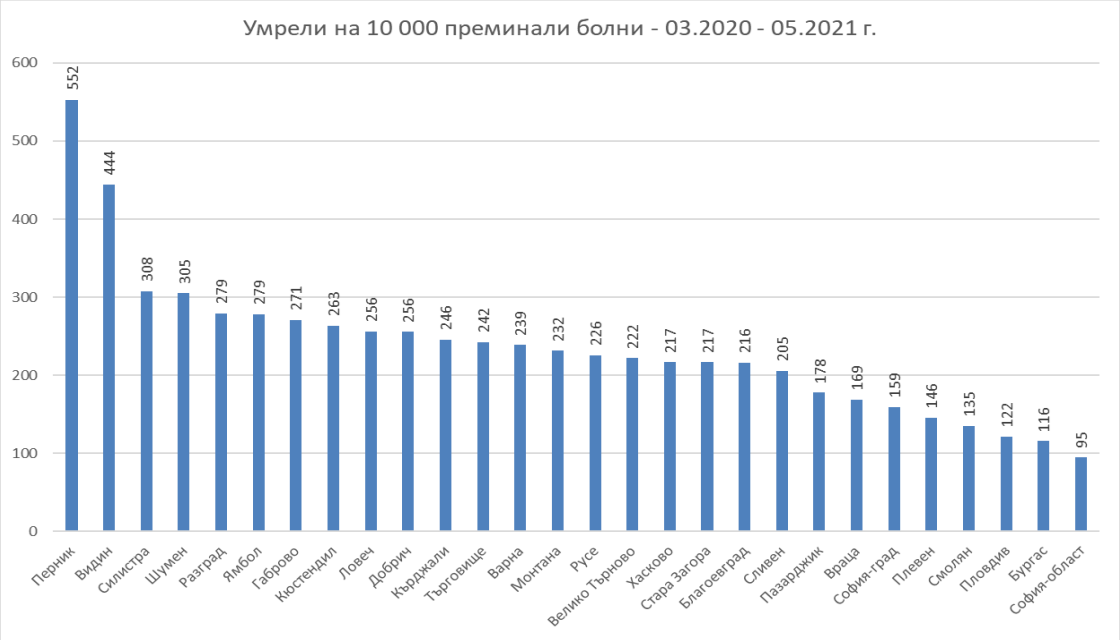
Fig. 71 Deaths by leading disease classes

Source: NHIF

The deaths per district per 10,000 patients show two distinct districts—Pernik[16] and Vidin. Both districts would be the subject of a separate study, but it can be assumed that the main reasons are probably the unfavourable demographic structure, the availability of specialists, and the indicator of Pernik could be influenced by the proximity and easy connection with Sofia—young and mobile residents of the district would prefer to be treated in a metropolitan hospital. In general, the available data do not provide a basis for drawing conclusions with a high degree of reliability. (Figure 72)

[16] When analysing the activities of the NHIF, it is noticeable that Pernik is one of the three districts where there is not a single test for COVID-19 paid by the NHIF.

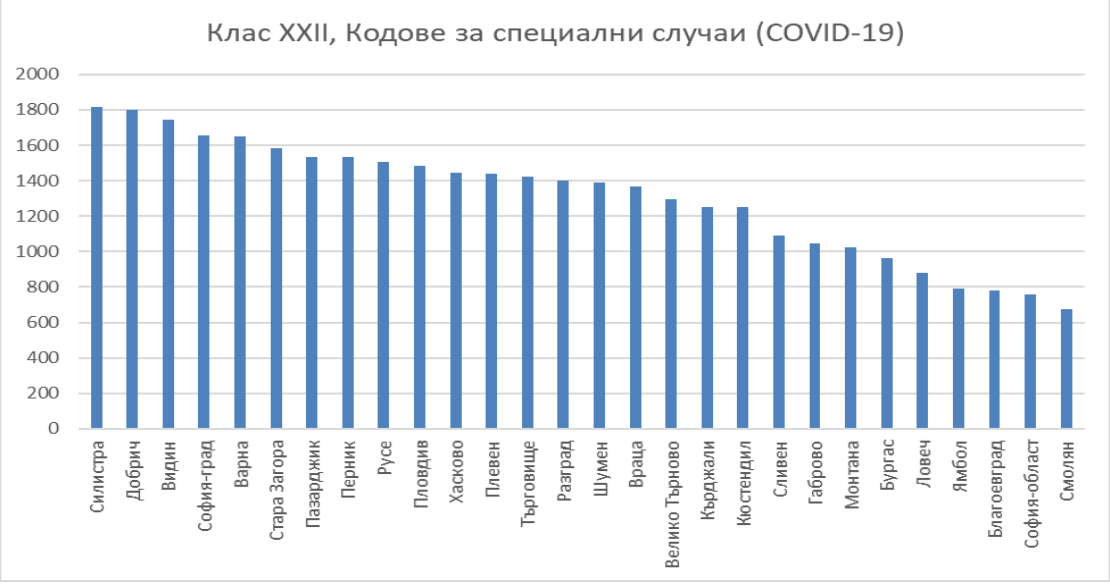
Fig. 72 Deaths per 10,000 patients by district



Source: NHIF

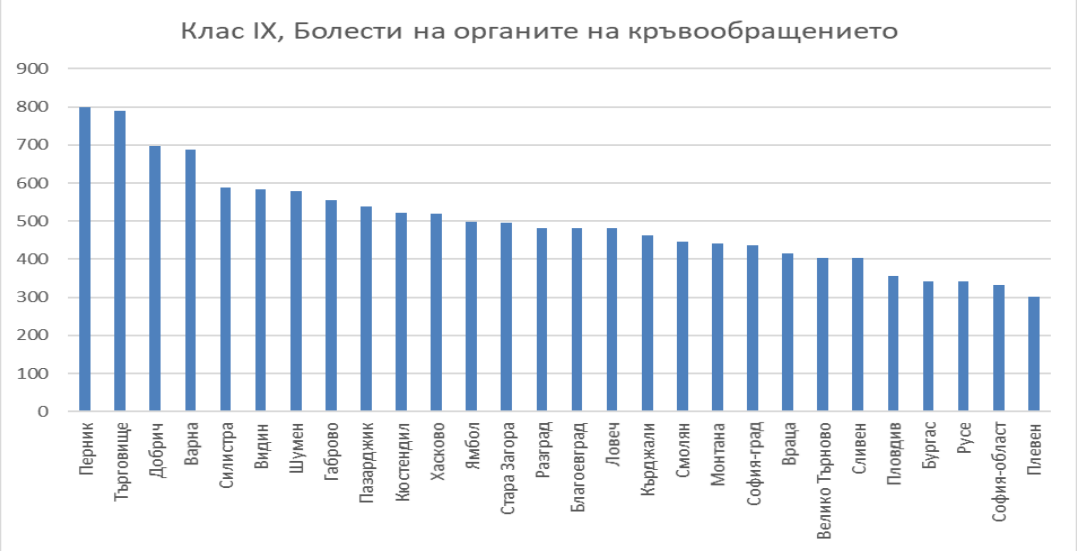
Additionally, an analysis has been made of the four classes of diseases that are the main causes of deaths by district and per 10,000 patients passed sick. Again, with the available data, no firm conclusion can be drawn about the causes of death in a given area, but they can be a starting point for further analyses, with a different design and other objectives. (Figures 73, 74, 75, 76)

Fig. 73



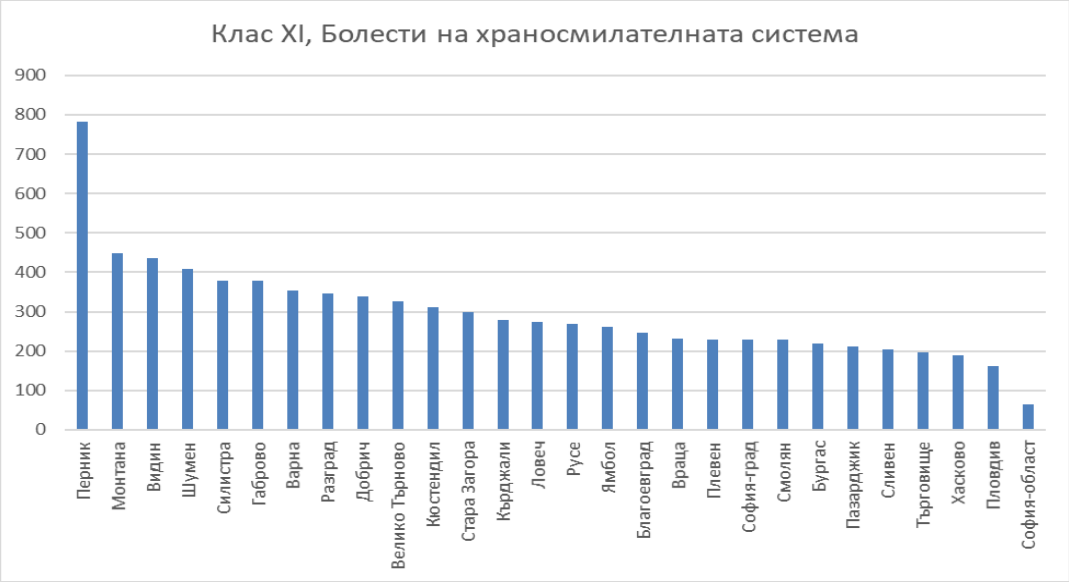
Source: NHIF

Fig. 74



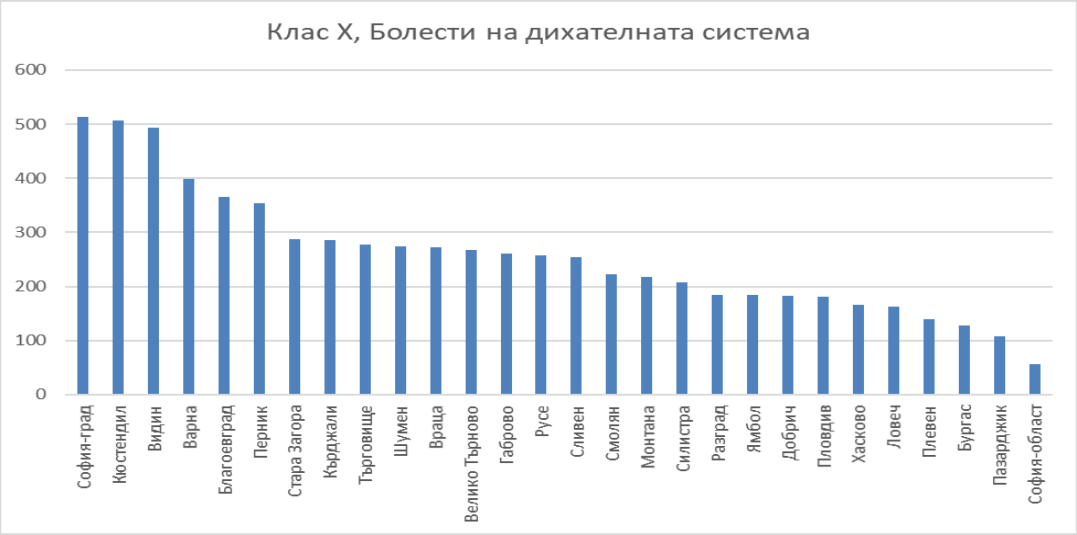
Source: NHIF

Fig. 75



Source: NHIF

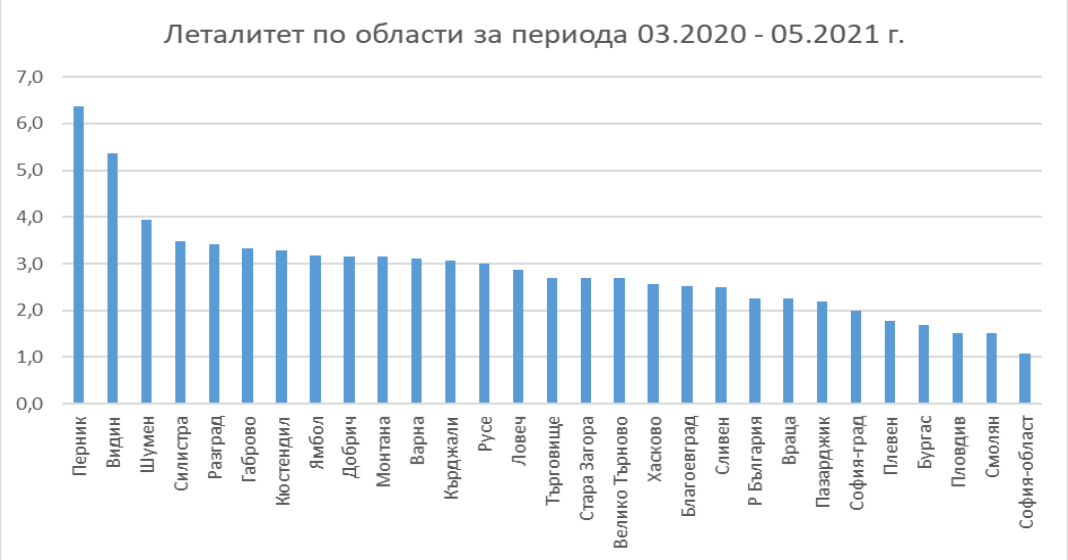
Fig. 76



Source: NHIF

The case-fatality rate is the ratio between the number of deaths from a particular disease (or group of diseases) and the total number of people suffering from the same disease (group of diseases). The result is usually expressed as a percentage. Hospital case-fatality rate is the ratio between the number of people who died in hospitals and the number of people who left hospitals (discharged and died). (Figure 77)

Fig. 77 Hospital case-fatality rate by district



Source: NHIF

This graph confirms the above observation that the most unfavourable ratio between deaths and discharges is in Pernik and Vidin. Hospital care in both districts should be monitored and analysed in more detail and, if necessary, action should be taken to improve their performance and, consequently, the satisfaction of residents of healthcare.

Findings

- The hospital care system has proved not quite prepared for the COVID-19 pandemic from the beginning of 2020;
- The health authorities have tried to react according to the situation, especially in the restructuring of hospital structures;
- The period from March to September has not been sufficiently utilised to take more adequate measures and actions in view of the expected escalation of the pandemic in the autumn and winter months.;
- Hospitalizations are down over 25% in 2020 compared to 2019;
- In some of the districts, due to an initial low availability of beds to the population, a situation was reached where almost half of the available hospital beds were treating patients with COVID-19;
- Most inpatient hospital deaths were under Class XXII, Special Case Codes (COVID- 19);
- Along with other, conventional classes of death-causing diseases, no explanation can be given for most deaths in 2020;
- It can be argued that the deaths did not occur on the premises of hospital care facilities.

Part 7

Analysis of the government decisions and the National Coronavirus Task Force

Chronology of the decisions of the Council of Ministers regarding the COVID-19 pandemic

For the purposes of this report, the decisions related to the pandemic from COVID-19 for the period 08.03.2020 - 31.05.2021 have been extracted from the Council of Ministers (CoM) website. Some of the more important decisions are reviewed in chronological order hereafter.

On 08.03.2020 a decision was passed to close hospitals with an identified case of COVID-19. The decision states that the Minister of Health should issue an order to place hospitals with an established case of COVID-19 under quarantine, and that these hospitals will only accept patients with surgical emergencies, as well as emergency cases of cardiovascular and neurological diseases. Along with this, a number of other crisis-related decisions were adopted, such as suspending in-person forms of training, banning the export of protective equipment, importing such equipment from Turkey, providing information to hospital facilities on setting up protocols for the treatment of COVID-19, and providing additional beds for COVID-19 infection when necessary.

On 12 March, the Council of Ministers declared a state of emergency in the country, and on 25 March decided to establish a logistical coordination centre for the distribution of protective equipment and supplies, and exempted all medical devices and goods related to the COVID-19 pandemic from customs duties and VAT.

On 27 March, the Council of Ministers approved two contracts with the People's Republic of China for the supply of protective equipment and medical devices (50 respirators worth a little over EUR 1.4 million).

A CoM decision of 30 March introduced compensatory measures for sectors affected by the pandemic—hotels, restaurants, sports and entertainment complexes, retailers and transport (the so-called 60/40 measure). Other sectors are assumed to be eligible for compensation upon proof of no less than a 20% reduction in revenues. Excluded from this measure are sectors such as agriculture, forestry and fisheries, education, human medicine, social services, as well as small producers and households providing employment. A decision was taken to increase the deficit by a total of BGN 4.2 billion, including BGN 700 million in funding for the BBR. A decision was also taken to increase public debt by BGN 10 billion.

In following meetings of the CoM, decisions were taken to import tests from China, to transfer and reallocate funds from EU operational programmes to other programmes that could finance activities to tackle the pandemic (over BGN 1 billion), to provide interest-free loans for unemployed people (up to BGN 200 million), and to channel funds (nearly BGN 870 thousand) to international organisations involved in the fight against the pandemic—the International Committee of the Red Cross, UNICEF, the UN High Commissioner for Refugees, the UN Office for Humanitarian Affairs and a number of other measures.

On 28.07.2020 a decision was taken to increase the budget of the MoH for 2020 by BGN 7,425 million in order to strengthen the capacity of medical institutions in the pandemic circumstances.

On 05.08.2020 it was decided to increase the budget of the MoH for remunerations of the administrative staff in the amount of BGN 10,526,600. An additional BGN 9,600,000 is approved to support state and municipal hospitals to cope with the pandemic. At the same meeting, decisions were taken to increase the budgets of the Ministry of Labour and Social Policy by BGN 15 million for front-line staff and BGN 29 million for additional remuneration for Ministry of the Interior personnel. Thus, in practice, a total of BGN 17 million has been allocated to support hospitals, while a total of BGN 44 million has been allocated to support front-line staff in other departments. If the funds for the administrative staff of the Ministry of Health are added, these funds increase to nearly BGN 60 million. Increased expenditures have been approved by various decrees for a number of other departments with indirect involvement in dealing with the pandemic, for which no calculations can be made from the published CoM decrees, but it is clear that the focus has been diverted away from the real needs of the country's health system and hospitals.

On 14.10.2020 the government allocated 2 100 000 BGN for the purchase of a medicinal product for the treatment of COVID-19 (*Remdesivir*), whereas on 20.11.2020 the government grants the EU the right to purchase vaccines from four companies with the possibility of concluding a contract with a fifth.

On 03.12.2020 the Government approves the National plan of the Republic of Bulgaria for pandemic preparedness, and on 7.12.2020 adopts the National Vaccination Plan against COVID-19 and designates a National Vaccination Task Force.

On 09.12.2020 the decision was adopted for additional expenditure in the amount of BGN 5 million for the purchase of equipment and other medical devices for the Medical Institute of the Ministry of Interior (MIA Hospital).

On 16.12.2020, the electronic prescription is introduced with an amendment to 'the Ordinance on the implementation of the right of access to medical care' and an additional BGN 65 million are granted for hospital care facilities. Up to BGN 50 million are provided for hospitals that will provide more than 50% of their bed capacity. It is envisaged that 55 hospitals in the country—municipal, state and private—will take over the main hospitalizations of patients with COVID-19.

On 22.12.2020 additional expenditures were approved in the budget of the MoH in the amount of BGN 150 million, of which BGN 105 million for the purchase of vaccines and BGN 45 million for subsidies for hospital care and additional remunerations for front-line medical workers. A further BGN 19,440,000 is also made available for the purchase of a medicinal product (*Remdesivir*). BGN 14,300,000 are also approved for the construction of an emergency call system. On 26 January, a decision is taken to step up counter-epidemic measures.

On 10 March 2021, a decree of the Council of Ministers provided additional financial resources from an operational programme (the Operational Programme 'Regions in Growth') to strengthen the capacity of the health system, envisaging the provision of isolated structures and the necessary

medical equipment for 105 hospitals in the country.

The CM decision of 9 April 2021 provided funds for additional remuneration for medical and non-medical staff working directly with COVID-19 patients and activities related to this, as well as in the administration of vaccines. The costs have so far been provided by the MoH through transfers to the NHIF, and with this decree, these costs will be out of the resulting savings from the 5% reduction in costs under other budgets and transfers (Article 106(2) of the State Budget Act 2021). This resolution orders the State representatives on the Supervisory Board of the NHIF to initiate an update of the methodology for the allocation of amounts paid by the NHIF for work under adverse conditions, including the additional remuneration of BGN 1,000 to frontline staff in the fight against the COVID-19 pandemic.

Apart from the officially published decisions of the Council of Ministers, there is a whole set of decisions, speeches and actions at the highest government level that are reflected in the media. A number of periods are outlined below.

The first is from March to the end of April (25.04.2020), when the possibility of liberalising the measures prior to the end of the state of emergency is announced. The main thesis being defended is that Bulgaria is being set as an example because it was the first to introduce the most effective measures, while the rest of the countries have been floundering and therefore have to pay a high price; people' s lives must be placed first, regardless of the possibility of economic losses; there must be funds in the first place for people on the front line and for pensioners; the government cannot afford to spend resources irresponsibly, to take on debt, it must wait.

The second period is from the end of April to 9 July. The main thesis advocated then is that Bulgaria is first in both introducing measures and in relaxing them; we have to learn to live with this virus in the same way as we live with other diseases; we have to learn to protect ourselves and to respect the rules; we will rely on self-restraint; the Bulgarian economy has started operating before the others; new measures should not be introduced because this will bring panic to the economic life; the health system is much better prepared.

The third period is from 9 July to 25 November. The main arguments being defended are that soft measures are needed; it is enough to keep distance, to disinfect, to wear masks and to increase caution; there is a firm stand against the imposition of other restrictions; businesses will not be closed; people's psyches must be preserved; there is a request to introduce a uniform protocol regarding measures at an EU level.

As a result of this media discourse, the following picture of public opinion emerged. Since the beginning of June, a process of strong public polarisation of public opinion on the restrictive measures has begun. Despite this, with the spike in the number of infections over the summer, attitudes are shifting towards an increase in fears, with around 60% expressing disagreement and less than 40% agreeing with the introduction of more restrictive measures. At the beginning of November, the responses are now 50.8% in agreement (21.8% somewhat agree and 29% strongly agree) versus 47.6% in disagreement (18.6% somewhat disagree and 29% strongly disagree), but again there appears to be a reaction in favour of increasing concern as the number of infected rises.

The fourth period is from 25 November to 9 March. During this period, the main thesis is that Bulgaria has managed its finances, economy and health measures in the best possible manner during the crisis; they have been the softest and most protective of people's psyche, while at the same time "enabling the economy to work well and cover the huge costs of the pandemic"; Bulgaria is the country with the most protective measures in the EU, while at the same time managing to contain the incidence of the disease; this is a masterful management of the crisis; we continue to ease measures due to the fact that our indicators are much better than all the countries in full lockdown.

The last period of media talk is from March 9 to the end of the month. The thesis that is being advocated is that we cannot put hospitals at risk and under pressure for a political dividend to compromise the best model that was so far carried through in Bulgaria; by 31 March, the most rigorous counter-epidemic measures will be implemented because people's lives and health are most important.

Findings

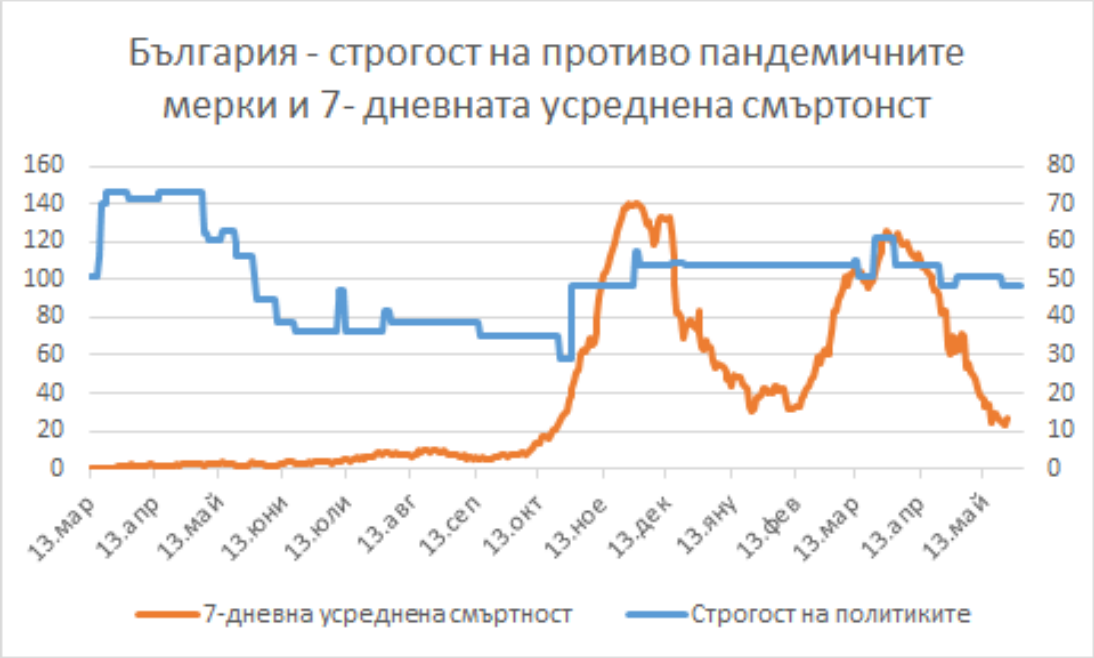
It is already evident from the Decision of 8 March 2020 that the Government's chosen strategy is to introduce a quarantine regime for hospitals and/or sectors where a contamination source has been identified, which in practice means to close these structures. The Government's decisions show, from the beginning of the period under review, a clear lack of understanding of the pandemic problem and the capacity of the health system to adequately address it. Instead of strengthening the capacity of hospital facilities and ensuring maximum separation of infected patients from the rest of the patient flow, restrictive measures of total closure were implemented, which did not take into account the remaining patients beyond those infected with COVID-19. The government's efforts are focused on providing protective equipment and disinfectants.

In the decision to compensate different sectors (the 60/40 measure) of the economy, the motivation for supporting certain sectors—mainly in the service and entertainment business—at the expense of key sectors of the economy, including human medicine, is not clear. At the onset of the pandemic, no substantial measures were taken to strengthen hospital facilities with the necessary equipment and oxygen therapy systems. There is no major financial support for hospital care until the end of 2020. It was only at the end of the year, after the first severe and frightening peak of infected and deadly cases, that the government began to allocate substantial sums of hundreds of millions of BGN. At the end of 2020, a National Counter-Epidemic Plan was adopted almost simultaneously with the Vaccination Plan. This is a clear confirmation of the general impression that the crisis has been managed chaotically, not on the basis of evidence and statistics, and without the necessary consultation with the relevant medical professionals. It was only after the catastrophic mass infections and deaths occurred that serious financial measures were taken, including the introduction of new prices for the pathways used to treat COVID-19 patients, as will be seen further below in the analysis of NHIF activities.

In terms of media coverage of the crisis, the lack of strategic planning and vision for its resolution is clearly visible. The conclusion is drawn that one of the main reasons for the ineffective handling of the crisis is the personal breakdown in trust in the government and the prime minister himself.

The public sphere is dominated by populist talk and a reassuring tone amid reportedly alarming data. This discrepancy between the media portrayal, which to some extent also corresponds to the degree of severity of the measures, and the actual mortality picture on a weekly basis is presented schematically in Figure 78, where the severity of the measures is calculated using certain indicators on an international basis. It can be clearly seen that the degree of restrictiveness does not coincide with the actual course of the pandemic, which further demonstrates the inadequacy in crisis management.

Fig. 78



Source: COVID-19: Government Stringency Index

Chronology of the decisions taken by the National Task Force

On 26.02.2020, by order of Prime Minister B. Borissov, the National Coronavirus Task Force (NCTF) was established. Major General V. Mutafchiyski, Head of the Military Medical Academy, was appointed Chief of Staff, with the other members Chief Commissar G. Arabadzhiev, Deputy Secretary General of the Ministry of Interior, Chief Commissar Svetlan Kichikov, Director of the Border Police of the Ministry of Interior, Boyko Hristov, Head of the Crisis Management Department, prof. T. Kantardzhiev, Director of the National Centre for Infectious and Parasitic Diseases, and Assoc. Prof. A. Kunchev, Chief State Health Inspector. The activities of the Staff consist of organizing, coordinating, summarizing and analysing all information related to the spread of the COVID-19 pandemic and informing the general public, as well as periodically briefing the Prime Minister and the relevant Ministers on the evolution of the situation related to the spread of COVID-19 and the measures and actions taken.

Immediately after its formation, the NCTF started its operations, with the first meeting setting the main guidelines and drawing up a timetable for the work of the NCTF. From the minutes submitted by the Chairman of the NCTF—there are 53 records in total for the period 26.02.2020 to 28.05.2020—it is evident that the staff met daily for the documented period, sometimes twice a

day. More than 130 briefings were conducted for about 100 days to inform the public. For the subsequent period of the staff's work until its dissolution there are no minutes submitted.

As early as the beginning of the pandemic, the NCTF analysed data on the state of hospital care, determining that nationwide the country was equipped with 740 infectious disease beds. The structures of the Infectious Diseases Hospital "Prof. Ivan Kirov" were still unusable at that time due to recently completed renovations. From the report of the Secretary of the NCTF, Assoc. Prof. Dr. Dimo Dimov – Head of the Department of Emergency Medicine at the MMA, it is evident that there is a readiness of the hospitals to open additional beds in case of possible spread of COVID-19 infection in the country. Initially, three hospitals in the capital have been designated to open infectious diseases beds—Pirogov hospital with 42 beds, Aleksandrovska with 70 beds, and the MMA with 42 beds.

Already with the first decisions of the NCTF, the delivery of 8000 pieces of protective clothing and masks is foreseen. Two more PCR laboratories for coronavirus testing are established in Varna and Stara Zagora, with the National Reference Laboratory as the main base.

On 03.03.2020 a decision is made to supply masks and clothing from Turkey.

On 5 March, an influenza pandemic was declared, with the minutes showing consideration of the possibility of the Infectious Diseases Hospital admitting coronavirus patients.

On 7 March the first patients were admitted to the Infectious Diseases Hospital for treatment.

On 11 March, the first positive case in MMA was registered. The first death from COVID-19 was in Pirogov.

On 14 and 15 March, proposals for behavioural algorithms, validation criteria, definitions and treatment guidelines were examined.

On 16 March it was decided not to introduce home quarantine for contact persons of the medical staff.

On 18 March it was decided to completely lockdown Bansko. The reason, according to unofficial data, is that 80% of tourists from Israel after their return to the country turned out to be positive for COVID-19.

On 19 March the government decision to transform Arena Armeec Sofia into a 500-bed military field hospital is discussed. On television the deployed beds in the sports hall are shown. The positive samples are 163.

On 22 March it was decided to allocate 10 vials of quinine for Pirogov and another 12 vials for RHI.

On 23 March, letters to district governors to transform sports halls to accommodate infected patients were discussed. It was decided that all hospitals should allocate beds for admission and treatment of COVID-19. The number of laboratories to take samples has been increased with 7 more—at BAS, RHI, Acibadem City Clinic Tokuda Hospital. All laboratories report positive samples to the National Reference Laboratory for confirmation.

On 25 March, a decision was taken to extend the period of sick leave issued by GP's and also to establish a logistics centre to determine the need for protective clothing. The staff takes a decision to extend the measures.

The minutes of 26 March state that tests by private laboratories are not paid for by the state.

On 27 March, it was decided to conduct screening by rapid (antigen) tests of certain population

groups.

On March 30, it was decided that every medical establishment for hospital care will provide beds and staff to treat COVID-19 patients.

On 14 April it was decided to slightly loosen the measures given the delay in the fulfilment of the immunisation calendar, scheduled surgeries are being brought back.

On April 16, a full lockdown is introduced for the village of Panicherevo. It was decided to organize a mass testing of all residents of the village. In the same record it is noted that there is a proposal from a company distributing diagnostic tests for coronavirus, to which apparently there is no affirmative response—it is claimed that there are many such proposals and they are all being assessed as "if necessary, contact will be made with the supplier companies" (Prof. Kantardzhiev).

On 18 April, a proposal of the RHI-Sliven for restrictive measures in certain areas was rejected on the grounds that at that time the number of confirmed persons suggested an active tracing rather than strict isolation.

In the minutes of 22 April, on the occasion of a letter from the Governor of Pleven, it is noted that the still low number of confirmed cases of COVID-19 in the village of Bukovlak does not suggest the introduction of a strict isolation restriction regime. A letter from an organization 'United Parents' was also considered, apparently calling for mass testing, with the impression from the minutes that the staff did not acknowledge this possibility (Prot. No. 43/22.04.2020). The same minutes reject the proposal to include veterinarians in the NOS.

On 23 April a decision was taken to reinstate children's immunisations.

The minutes of 26 April show that there is some discrepancy between the proposals of the Chief State Health Inspector to introduce a set of counter-epidemic measures and the opinion of the head of the NCTF, Gen. Mutafchiyski, who declared that the proposal in question essentially constituted an economic and political issue which should be dealt with by the relevant departments. It is clear from this protocol that the NCTF does not perceive its functions in their entirety, but divides them into purely medical and political-economic functions. The same minutes also note a proposal by Assoc. Prof. Kunchev to organise and conduct serological tests (ELISA method) on a representative sample from Plovdiv in order to detect antibodies against coronavirus. Subsequently, this initiative was discontinued as it turned out that a minimal percentage of Plovdiv residents had antibodies. This decision is particularly significant for the evaluation of the epidemiological approach to events by the NCTF, since mass antibody presence cannot be expected at the beginning of a pandemic. It is the mass testing for the presence of coronavirus either by PCR or by rapid antigen test that would be the logical behaviour at the onset of the crisis. This protocol again reveals a certain hesitancy in the decisions of the NCTF regarding the economic and political impact of the measures. In this regard, Gen. Mutafchiyski stated that given the length of the restrictions, some relaxations are also being discussed and applied on an international scale. The protocol also stresses that the opinions of the NCTF are merely advisory and "final decisions are within the powers of the competent authorities."

On 28 April, a letter from the Minister of Health was discussed regarding regional allocation of funds for PCR reagents, rapid antibody tests and rapid antigen tests. The decision was taken to allocate the funds to priority regions such as Vidin and Kyustendil, with the RHI's receiving BGN 40,000 each for consumables.

On 29 April, an emerging coronavirus outbreak at the Oreshets nursing home was discussed. Against this background, decisions are taken for mass testing of all residents and staff, as well as for the preventive hospitalization of the persons at risk (concomitant diseases, elderly age).

On 1 May, a meeting of the NCTF was held at the Council of Ministers in the presence of the Prime Minister, the Minister of Interior and the Mayor of Sofia Municipality. At this meeting, possibilities were discussed for a phased relaxation of the introduced counter-epidemic measures, and it was recorded that the Prime Minister was awaiting concrete proposals on the measures, which could be lifted in the coming days. These minutes again show the hesitancy of the NOS in view of pressures unrelated to medical considerations. The Prime Minister instructed the Minister of Health to issue an appropriate order relaxing certain measures and dropping certain restrictions on wearing masks, visiting parks and mountains, etc.

On 3 May, decisions were taken on further easing of the measures.

On 21 May, the NCTF decided to admit Czech specialists without placing them under quarantine and only on the grounds of a submitted declaration and a negative PCR test.

On 28 May, the NCTF considered inquiries to the MoH regarding the payment of PCR tests, as well as a mechanism to adequately fund laboratories and medical facilities with the introduction of the *clinical pathway COVID-19*. At this meeting it was proposed to find an effective solution for the payment and additional funding of these units as a way to compensate for the reduced admission of patients with other diagnoses. The need for a sufficient numbers of PCR tests was reiterated at this last protocol presented by the NCTF.

Findings

The documents presented, covering the work of the NCTF, are for a very brief period of the pandemic and do not give a clear picture of the conduct of the staff during the two major waves in late 2020 and early 2021. It becomes evident from these protocols that the work done by the staff is enormous in scale and workload of the people working in it. Many of the regulations required to contain the pandemic were developed during this period—plans for operating in an epidemic situation were drawn up for the district hospitals, algorithms and forms for epidemiological investigation of contacts were created, border controls and the control of citizens entering the country were reinforced, and a range of other important decisions were adopted. The vast majority of these have been formalised as orders of the relevant Minister for the period under review. Other orders are based on decisions of the Council of Ministers, while not all of them are the result of NCTF recommendations.

The composition of the NCTF is not entirely appropriate to the challenge of the pandemic. It is composed on the principle of a military structure that has to solve tasks in a quasi-military situation. The lack of sufficient medical expertise in the NCTF—such as infectious disease specialists, virologists, epidemiologists, pulmonologists, etc.—has an impact on the decisions taken to deal with the pandemic.

Along with a number of measures that are necessary and medically sound, some have been identified as inconsistent or half-hearted, and some unnecessary due to the fact that they are not based on sufficient medical reasoning. Examples of this are the several attempts at epidemiological surveys that have failed (Plovdiv – antibody testing in the face of low numbers of infected cases), and the swift cancellation of counter-epidemic measures before there is clarity on the extent of the pandemic in the country.

The allocation of beds in sports halls on the model of military field hospitals is completely inconsistent with the particularities of the epidemic situation. The deployment of beds in an

enclosed area is adequate in situations of mass emergencies, martial law or other catastrophes, but is totally inadequate in dealing with a pandemic and betrays a lack of expertise in this matter.

Requiring every hospital to provide beds for the treatment of patients with a coronavirus infection is another completely inadequate measure from an epidemiological point of view, given what is occurring in the country as a result of these decisions, namely the mass infection of all medical departments, including the medical staff.

The lack of a decision to conduct mass testing of the population and to ensure sufficient testing is another example of insufficient medical logic in the actions of the NHS. In a situation where the international situation suggests that what is happening in a number of European countries will inevitably happen in this country, there is no firm solution for mass testing of the population. This fact, together with the lack of a working information system, subsequently creates great uncertainty about the true extent of the pandemic in Bulgaria.

In the spring of 2020, an attempt was made to identify risk groups known to be at greater risk from the virus, namely adults over 65, living in long-term care or nursing homes, with chronic diseases such as COPD, asthma, cardiovascular diseases, immunocompromised, including those being treated for cancer, diabetes, kidney disease, liver disease, obesity (BMI over 40). At the order of the Deputy Prime Minister Tomislav Donchev, the NCPHA presented a summary of persons with chronic diseases in Bulgaria (Table 2). No systematic solution of the NCTF for selective prevention of groups at risk resulted from this, which would have limited not so much the spread of the pandemic but rather the number of victims that were made. The only solution in this regard can be found in the minutes of 19 March, when the restrictions for persons over the age of 65 were increased.

Table 2

Reference for high-risk patients by groups		
Number of persons with BMI >= 40		29 700
Pregnant		31 340
Health-insured person over 65 with choice of GP		1 516 005
Population aged => 65 yrs.		1 785 941
Reference for high-risk patients by ICD		
Name ICD	**Code ICD**	**Number**
Disease caused by human immunodeficiency virus [HIV], unspecified	B24	4
Diseases of the endocrine system, eating and metabolic disorders		
Insulin-dependent sugar diabetes	E10	26 968
Non-insulin dependent sugar diabetes	E11	344 856
Obesity due to excess calories	E66.0	2 419
Medicated induced obesity	E66.1	17

Extreme obesity with alveolar hypoventilation	E66.2		182
Other forms of obesity	E66.8		8 891
Obesity, unspecified	E66.9		6 076
Total		389 409	
Diseases of the circulatory organs			
Acute rheumatic endocarditis	I01.1		9
Acute rheumatic myocarditis	I01.2		2
Acute rheumatic disease of the heart, unspecified	I01.9		8
Rheumatic mitral insufficiency	I05.1		162
Mitral stenosis and insufficiency	I05.2		267
Other diseases of the mitral valve	I05.8		82
Mitral valve disease, unspecified	I05.9		89
Rheumatic aortic stenosis	I06.0		76
Rheumatic aortic insufficiency	I06.1		54
Rheumatic aortic stenosis and insufficiency	I06.2		60
Other rheumatic diseases of the aortic valve	I06.8		22
Rheumatic disease of the aortic valve, unspecified	I06.9		34
Tricuspid stenosis	I07.0		2
Tricuspid insufficiency	I07.1		18
Other diseases of the tricuspid valve	I07.8		3
Disease of the tricuspid valve, unspecified	I07.9		2
Combined involvement of the mitral and aortic valves	I08.0		94
Combined involvement of the mitral and tricuspid valves	I08.1		29
Combined involvement of the aortic and tricuspid valves	I08.2		6
Combined involvement of the mitral, aortic and tricuspid valves	I08.3		36
Other diseases of several valves	I08.8		18
Disease of several valves, unspecified	I08.9		35
Rheumatic disease of the endocardium without specification of the valve	I09.1		2
Chronic rheumatic pericarditis	I09.2		1

Other specified rheumatic diseases of the heart	I09.8	5

Source: NHIF

All NCTF meetings start with a briefing on the status of patients admitted to the Department of Infectious Diseases of the MMA. This creates the impression that the attention of the heads of staff is mainly focused on the central level, without covering or at least reflecting the overall picture in the country.

The NCTF's public appearances highlight that our mothers and fathers, our grandmothers and grandfathers are under unprecedented threat. In spite of the alarming and threatening statements that have created serious panic and fear within the population, the restrictive measures imposed have not had the expected effect. The reasons are that these measures are not subject to medical and epidemiological logic, but are taken at random, in accordance with current events. In fact, 'the hammer and the dance'[17] recommendation of WHO experts has not been implemented, or if so, it was under pressure from the vested corporate interests of various groups.

At the beginning, the pandemic has a clustered character and the measures of the NCTF follow this path by isolating certain populated areas. Unfortunately, the records show that these measures are also inconsistent—in some cases a complete lockdown is imposed (Bansko, Panicheri) while in others it is decided not to apply such measures in spite of signals and letters from local authorities. The general impression from this period of crisis management is that at the beginning of the pandemic, decisions of a predominantly medical nature prevailed, but from a certain point on they became political, ignoring medical evidence. In other words, the decision-making is becoming driven by political will and the local conjuncture rather than strict medical evidence.

As a matter of fact, it should be stressed that the experts and specialists in the NCTF are faced with a unique situation, which is not exclusive to Bulgaria. The lack of clear guidelines, recommendations and medical analyses of the new global threat, the lack of scientific facts about the nature of the virus are creating a general sense of uncertainty and an insufficiently strong foundation on which to build an adequate strategy. This condition of the NCTF experts is clearly expressed in the statement of the Chairman of the Staff in one of the minutes of May, where he points out that society must adapt to the reality: "...*in the absence of a vaccine, effective treatment and the impossibility of determining the end of the pandemic, a balance will have to be sought between counter-epidemic measures and the restoration of the normal rhythm of public life*".

Against this background of uncertainty and ambiguity about what is happening domestically and internationally, the insufficient role of respected global organisations such as the WHO, which for a certain period since the beginning of the pandemic emitted contradictory messages to the public regarding the effect of one or another medicine, the need for rapid testing, etc., should also be highlighted. This uncertainty on a global scale, as well as the actions of the former US President Trump with regard to the WHO, set a very serious precedent in the minds of people who had no way of navigating the situation. All of this, combined with the political influence that the Staff had

[17] The idea of 'the hammer and the dance' represents a rhythm of restrictive measures followed by a period of easing to allow hospitals time to recover and businesses time to survive. However, the decisions on the sequence of restrictions and relaxation of measures must rely on maximum awareness of the extent of infection in the population and the course of the pandemic.

on their back from the highest level of government, and the ambivalent attitude towards the professionals there, from showing high confidence to outright discrediting the members and the President himself in public, has led to a serious undermining of public confidence in the institutions. If any criticisms could be formulated of the people at the NOS, who without exaggeration have worked with absolute dedication, these are that they have probably not found sufficient courage and fortitude to place the medical and public health priority required firmly above all other influences in one or other direction. Or, to put it another way, an analysis of the decisions made suggests that the crisis was managed politically and authoritarian rather than professionally and medically.

One conundrum remains the decision to limit planned hospital admissions with few exceptions and elective surgeries. From this decision, which—in an unpublished report on the media aspects of the COVID-19 pandemic written in early 2021[18]—is explained in terms of practice in other countries[19], a cascade of problems follows: from the postponement of regular check-ups for chronically ill patients, which in many cases can lead to their exacerbation and subsequent emergency hospitalization (which puts additional strain on the emergency care system), to the emptying of non-COVID-19 wards and the shortfall in hospital payment limits. The response of the NHIF has been that it only pays for performed activity, leading to dissatisfaction on the part of the Bulgarian Medical Association and the frontline doctors.

However, of all the decisions made by the NCTF, the Council of Ministers and the two Health Ministers, in our judgement the most unfortunate is the decision to evenly distribute beds for coronavirus patients across the hospital network. This decision, subsequently supplemented and expanded, as will be seen from the orders of Minister Ananiev and Minister Angelov, has in fact led to the diffuse spread of the virus throughout the entire health network, infecting a large proportion of medical staff and patients respectively. In practice, there is no clean place left in the country to treat patients outside the COVID-19 infection. It is probably unfeasible to establish "clean" hospitals given a number of circumstances—location, equipment, staff willing to work there, etc. This is further illustrated by the attempts to identify such hospitals in Sofia and Plovdiv, which proved unsuccessful. What is not considered, however, is that not all hospitals can allocate separate corridors, entrances or separate buildings for COVID-19 treatment. The result is the closure of other wards and even entire hospitals for one or two cases[20] and the restriction of uninfected persons' access to medical care. It should be stressed that at the peak of the pandemic in the second half of 2020, there was not a single hospital or ward closed, i.e. this measure proves to be completely unnecessary and overburdening.

[18] "Methods of disinformation on the measures and vaccines in the coronavirus pandemic and the role of the Bulgarian media", Galina Karamotcheva, 08.02.2021.

[19] According to G. Karamotcheva the reasons are three: freeing places for COVID-19 patients in intensive care units, protecting other patients, and protecting the personnel. As will be seen later in this report, it is this decision that has led to one of the main causes of high overall mortality—a deteriorated access to the health system.

[20] In a well-known metropolitan private hospital, due to a VIP patient admitted with COVID-19, the entire hospital was closed. In other cases, wards are closed for an extended period of time along with the staff (‘Pirogov’, ‘St. Naum’, etc.). It should be stressed that at the peak of the pandemic in the second half of 2020, not a single hospital or ward was closed.

Part 8
Analysis of the activities of the Ministry of Health (MoH) management, as well as of the Regional Health Inspectorate (RHI) system, the National Centres for Public Health (NCPHA, NCIPD[21]) and the National Health Insurance Fund

Orders of the Ministers K. Ananiev and K. Angelov for the period 1 March 2020 - 31 May 2021

125 orders of Minister K. Ananiev and 105 orders of Minister Angelov related to activities concerning the COVID-19 pandemic were examined.

Minister Ananiev's orders initiate the declaration of an influenza pandemic on 05.03.2020 and the suspension of women's and children's consultations, prophylactic examinations, scheduled hospitalizations and appointments, as well as prophylactic immunizations from the immunization calendar.

An order dated 08.03.2020 instructs the suspension of educational activities in the districts of Gabrovo and Pleven, as well as all mass events in the two districts and elsewhere—the first introduction of restrictive measures. A further order of the same day closes the two district hospitals in Gabrovo and a 14-day quarantine is imposed.

An order dated 11.03 directs the RHI to make the necessary arrangements to increase the bed stock. A quarantine regime is also imposed on all hospital care facilities where patients are found infected with COVID-19. All contacts with the wards where infected patients have been detected is suspended. The wards are sealed off along with the remaining patients. Hospital directors are instructed to draw up action plans in the event of the presence of COVID-19 patients and to ensure continuity of the treatment process.[22]

On 13.03.2020, mandatory restrictive measures are introduced throughout the country, in all sectors, and with planned surgeries, elective admissions, female and child consultations, transplants, preventive examinations and immunizations, as well as appointments being cancelled in the health sector. The wording of the order does not make it clear whether patients with COVID-19 symptoms could be admitted under this regime.

An order dated 16.03.2020 bans the entry of foreign nationals into the country, listing a number of countries that fall under this ban. Temporary border crossing points are established in Gyueshevo, Vidin, Makaza, and others.

Order 01-129/16.03.2020 defines for the first time an isolation regimen for confirmed cases of COVID-19, specifying a home regimen for persons with a mild course of the disease and mandatory hospitalization for adults over 60 years of age regardless of the severity of the course, persons with accompanying immunocompromising diseases regardless of severity, those with a severe clinical course, and those for whom home treatment and isolation are not an option regardless of the severity of the course. This provision effectively blocks the entire hospital system, as it—on the one hand—saturates hospitals only with COVID-19 infected patients, and on the other, prohibits access to all other persons in need of hospital care. The consequences of this

[21] The report on the activities of the NCPHB is provided in the Annex.

[22] There is no information about these plans in the official documents to which access is available.

measure are serious and multifaceted, ranging from the mass contamination of medical staff to the occupation of beds by patients who do not need to be in hospital. In short, there has been a failed attempt at some kind of selective prevention of groups at risk, using badly needed hospital facilities, without considering the need for specialised treatment for severe cases and the unnecessary burden on staff. On the other hand, hospitals remain empty in terms of other specialties due to the ban on admissions. This is affecting their budgets, and there are still 7 months to go (1 November 2020) until the adjustment in the prices of the clinical pathways that account for the treatment of COVID-19 patients.

The next order of 17 March provides for quarantine measures for foreign nationals, as well as provisions for the epidemiological surveys done by the RHI, and the monitoring of COVID-19 positive persons by GP's if they are on their registers.

On 17.03.2020 a full shutdown of Bansko is ordered.

Subsequent orders opened new checkpoints, specified crossing regimes for foreign nationals and heavy goods transport, the restrictive measures are tightened in all sectors, checkpoints at the exits of district towns are established, time corridors for shopping for the elderly over 60 are introduced, etc.

On 25 March, an order was issued for mandatory registration of COVID-19 cases under the Ordinance on Registration and Reporting of Communicable Diseases. The functions of the various institutions in the health system for the processing and exchange of incoming information are described, as well as the organisation of the epidemiological survey of contacts by the RHI. Chloroquine is included as a medication for the treatment of patients with COVID-19.

On 27.03.2020 Minister Ananiev issued an order designating hospitals for the treatment of mild cases of COVID-19 and those for the treatment of severe cases. This order instructs the directors of the hospitals to take measures to conclude an annex to the National Framework Agreement (NFA) for the implementation of clinical pathway 104, under which these patients will be treated in accordance with the terms and conditions set by the Supervisory Board of the NHIF. This order betrays an ignorance or unwillingness to follow the legal procedure for amending the NFA and signing annexes. It lacks the main contractual partner, the Bulgarian Medical Association (BMA), and the initiative to initiate the legal procedure for this. Perhaps this is one of the explanations why the three clinical pathways and the two procedures that account for the treatment of COVID-19 patients were correct financially only on 1 November 2020. There is serious confusion in the issuance of the orders and a lack of a clear concept to deal with the situation.

On 30.03.2020 the imposed lockdown in Bansko was cancelled and general counter-epidemic measures were introduced.

By an order dated March 30, all persons are ordered to wear protective gear—masks in indoor and outdoor places. On 31 March, the previous order's point 9, making it compulsory to wear masks indoors and outdoors, was repealed. On 02.04, teaching practices and traineeships are allowed to be conducted at the Academy of the Ministry of Interior.

On 06.04, measures for farmers' markets are eased and existing additional restrictive measures introduced by local authorities are lifted.

On 06.04, the Unified Information System for the registration of COVID-19 is introduced. The

institutions with access to the system are listed (the NCPHA and NHIF are not included).

On 11.04 the mandatory wearing of masks—indoors and outdoors—is ordered again (the revoked point 9 of the previous order is amended).

On 14.04 a lockdown is enforced for the village of Panicherevo. On 15.04 the cooperative markets and the exchanges are closed, and vehicles are halted for entering and leaving Sofia.

On 20.04 there is a partial lift on the ban on scheduled admission to the children's consultation and the mandatory immunizations, but the ban on transplants procedures remains. On 21.04 assisted reproduction activities are suspended, except for procedures already started.

On 28.04 the measures for Panicherevo are dropped (after 14 days had passed). The next order of 29.04 lifted the ban on scheduled immunizations.

The order of 30.04 introduces concepts of test results for COVID-19—possible, probable, confirmed. The number of laboratories testing with PCR tests is increased.

Subsequent orders from 01.05 lift some of the restrictions on visits to parks and public places. Further orders followed with more or less contradictory content, which does not reflect a possible sustainable strategy to deal with the pandemic. On 11.05 sports facilities and activities are opened without public. On 14.05, bars, nightclubs, restaurants and shopping malls are closed. Indoor and outdoor sporting events are suspended, while educational activities, classes and conferences are stopped. A ban on entry into Bulgaria is introduced. On 15.04 amusement and gambling halls, bars, shops, restaurants, etc. are closed. A complete ban on public events is imposed. The bans remain in force until 26.05, when the measures are again partially relaxed, allowing the opening of restaurants, gambling halls and malls. Subsequent orders of 02.06 and 03.06 relax the measures on mass sporting events – football matches are allowed under certain conditions (which are generally not respected by the public).

On 12.06, the order for designation of medical treatment facilities for COVID-19 is revoked. Hospitals are now also included as sites for PCR tests. The latest order dated 17.07 has a list of hospitals where citizens can be tested with PCR tests.

The first order that was issued by Minister K. Angelov, which has been examined for the purposes of this report, dates to 27.07.2020. It introduced restrictive measures regarding the entry of citizens from other countries into Bulgaria. This order is interesting in that it allows citizens from a fairly large number of countries to enter the country without presenting any document. On 31.07 an order was issued with a similar content, where the exceptions for citizens to enter the country without requiring some kind of document are very numerous—the order looks more like introducing a permissive regime than a prohibitive one. The list of exceptions to the prohibitive regime for foreign nationals to enter the country remains the same. Subsequent orders have increased the number of laboratories and hospitals in the country that are authorised to conduct PCR tests. As of 8 September, there were 45 of them, 19 of them located in Sofia. On 06.10. the drug *Remdesvir* was included in the list of medicines paid by the NHIF.[23]

[23] The late inclusion of this drug, which has been shown to be highly effective in clinical practice, is largely due to conflicting messages about the drug's effect from the WHO. Instead, the chloroquine drug was supplied in such quantities as to allow the waiver for its export. Clinical results have shown that the medicine has low efficacy in treating COVID-19 and has side effects.

On 13.10.2020, the presence of audience at a football match at the stadium "V. Levski" is increased to 30% occupancy. On 21.10.2020 the counter-epidemic measures are extended with the exemption of restaurants, sports grounds, congresses, etc. On 22 October the occupancy of seats for spectators at indoor and outdoor sports events and football matches is increased to 50%.

On 23.10, however, planned admissions to hospitals in districts with a morbidity of more than 120 per 100,000 population are suspended again. Elective surgeries were also suspended. COVID-19 beds are mandatorily opened in in-patient care facilities and oncology centres. The latter is in strong contradiction to previous guidelines for selective prevention of at-risk groups, in particular patients with oncological diseases.

On 27.10 school activities are suspended and strict counter-epidemic measures are introduced, with the exception of the Sofia Open tennis tournament.

The 06.11 order attempts to secure information flows through mobile apps. Detailed instructions are given to the RHI's on the activities they carry out, access to the National Information Portal is expanded to include divisions of the Agency for Social Assistance (ASA), the Medical Supervision Directorate and the National Centre for Transfusion Haematology. No access has been granted to the NCPHA.

The next few orders reiterate the restrictions on school activities against the background of maintaining a permission of 30% occupancy for cultural and sporting events, whereas for the latter is expected to have no audience, except for the Sofia Open tennis tournament. Restaurants are open from 06:00 to 23:00. Malls are also open under certain restrictions. As of 25.11.2020, the number of laboratories that can perform PCR tests is now 81, 30 of which are located in Sofia.

On 25.11, educational activities and all public events are suspended, shopping malls are closed, etc. The percentage of mandatory beds for COVID-19 is increased to 20% of the capacity of inpatient care facilities and oncology centres.

On 18.12 a ban is imposed on the export of 11 medicinal products, which indicates a shortage of these products within the network. Attendance of students from 1st to 4th grade is allowed, nurseries and kindergartens are allowed to open, theatres and restaurants remain at 30% occupancy, shopping malls remain closed.

On 23.12 the campaign for immunization of the population against COVID-19 was launched.

On 15.01.2021, elective admissions and operations in hospitals are reinstated. Oxygen exports are allowed again, which implies assured quantities for the country.

On 11.02.2021 the list of PCR test laboratories is 104. The participation of GP's in the vaccination campaign is allowed (almost two months after its start).

On 26.02.2021 the measures are eased and nightclubs and bars, gambling halls (up to 50% capacity) and congress events (up to 30% capacity) are allowed to open.

On 10.03, a ban is introduced on the export of Fraxiparine and Heparin (anticoagulants with great efficacy in the treatment of COVID-19), which means that they are depleted in the network.

On 15.03 the educational activities and circuses are opened. Three days after, on 18 March, all educational institutions, sports, cultural, entertainment, etc. events are closed again and strict restrictive measures are introduced in all sectors. Physical presence at work places is permitted for

up to 50% of employees.

An order dated 08.04.2021 introduces scheduled attendances for students by class, while gyms, pools and restaurants—with up to 30% occupancy—are opened. Gaming halls and casinos are also opened on 16.04 with up to 50% occupancy (theatres are up to 30%).

From 16.04.2021, the measures for the different sectors are successively loosened. On 11.05 the number of immunization sites is already at 376 and the number of PCR test sites is 116.

Findings

The orders of the two ministers for the period under review are not that different from the decisions of the Council of Ministers and the NCTF. They detail the management of the crisis, but they contain the same strategic errors that have been mentioned earlier:

1. A lack of a comprehensive concept to tackle the pandemic.
2. A lack of sufficient information about what is happening in the country.
3. Half-heartedness and inconsistency in the counter-epidemic measures.
4. Selectivity for certain permission regimes.
5. Taking conjectural decisions that follow certain events, rather than based on epidemic forecasts (the presence of mathematicians in the NOS does not contribute much to the implementation of preventive measures).
6. The—in many instances—obedience to political logic and expediency, instead to medical reasonings.
7. Avoiding conflicting viewpoints and a lack of consultation with the relevant specialists (the formation of the Medical Advisory Council at a certain stage in the pandemic was a decision of the Prime Minister and resulted from a number of conflicting views from other specialists that contradicted the official policy).
8. Making decisions that contradict the epidemiological science and knowledge, etc.

The overall impression of the orders issued by ministers Ananiev and Angelov is that they follow a different political-populist expediency and do not display the energy and courage to defend medical logic and medical science. The most drastic examples of this assessment are several orders which, in our opinion, contribute to, rather than prevent, the spread of the epidemic outbreak.

First of all, this is the decision to open beds for the treatment of COVID-19 patients in all hospitals in the country, including (!) in oncology centres, where the most at-risk contingency of patients is concentrated.

The second measure that adds to the negative impact on the system is the ban on elective admissions and elective surgeries for all hospitals in the country.

The third measure is the order that only COVID-19 patients, including those with a mild course of the disease and even those who cannot be isolated in a home environment, should be admitted for hospital treatment. The result is overloading hospitals with only one type of patients, leading to a cascade of problems:

- the overloading of some hospital wards while emptying others (in financial terms this leads to a paradoxical reduction in the income of some of the hospital teams due to their shift – even the extra 1000 BGN for working on COVID-19 is not enough to cover the lack of

patients in the other wards. Thus, when they return to their old workplace, they are paid less than their normal wage due to the lack of patients outside COVID-19. The NHIF's decision to pay 85% of the funds on a historical basis in this case had an indirect role to play in this situation, albeit one that makes sense—the NHIF pays for work performed);

- the risk of infecting all medical staff—infected medics leave their jobs for long periods of time and this further increases the shortage of medical experts;
- the risk of exacerbating all chronic diseases and those requiring recurrent treatment in a hospital setting—the accumulation of medical problems due to untreated and unmonitored chronic diseases leads to their exacerbation and even death, which is illustrated by the high overall mortality rate in addition to that caused by the pandemic;
- limiting access to hospital care for all non-COVID-19 diagnoses also translates into an increased overall mortality for 2020.

In conclusion, it must be said that despite the honest efforts of all medical supervisors and experts to respond adequately to the threat, overall, the management of the crisis has tended to be rather political than medical. In addition to a number of consequences that are outlined in this report, one very important consequence is the discrediting of the authorities and institutions responsible for dealing with the pandemic, which opens up space for conspiracy theories, politicking, speculation and unprofessional media appearances. As a result, it generates distrust in the efforts of the authorities to tackle the pandemic, including anti-vaccination sentiments. All this requires significant efforts to restore trust in institutions and the professionalism of health workers and their supervisors.

Analysis of the RHI system

The data for this analysis is scattered throughout almost all of the other sections of this report, because the RHI's are a major source of primary information on the COVID-19 pandemic. Overall, it should be emphasized that these entities entered the pandemic in a poor organizational, staffing, and financial state—at the very least, not in line with their expected responsibilities and the tasks they were charged with during this period. The underlying causes of this poor state of affairs are complex and can be sought back at least a decade. Over the last two decades, the system of RHI's has undergone a number of transformations which, on the one hand, have burdened them with additional duties and, on the other hand, have exhausted the staff potential of these structures. The pandemic has made it clear that their role in the health system is of the utmost importance, as it is directly relevant to the main objective of any health system—strengthening public health. It is evident that Bulgaria entered the pandemic with a very low level of public health, as reflected in the health and demographic indicators, which the authorities and the general public are informed about periodically and in specific forums dedicated to this topic.[24]

Already since the beginning of the pandemic, RHI's have been actively involved in conducting

[24] The reports on the health of citizens, which are prepared annually on the basis of data from RHI's and other institutions, are the main documents reflecting the state of public health in Bulgaria. These reports are presented by the Minister of Health to the Parliamentary Committee on Health, but that concludes the subject of public health at the governance level. In addition, the poor health and demographic situation of the country's population is being highlighted in a number of forums and round tables, both in Parliament and elsewhere, as well as in a number of reports by various organisations and institutions (WHO, UNICEF, BAS, etc.). These reports do not provoke any reaction on the part of the health care authorities.

epidemiological surveys to track the infected, a process that avalanched in the autumn of 2020 and led to the exhaustion of the staffing capacity of RHI's to take on these tasks. To these duties are subsequently added the laboratory studies for COVID-19 and the involvement of the RHI in the vaccination process. It is no exaggeration to say that the role of RHI in dealing with the pandemic is crucial, despite the shortcomings of crisis management at a central level.

Analysis of the activities of the National Centre for Public Health and Analysis (NCPHA)

The NCPHA has been carrying out its ongoing tasks since the beginning of the pandemic without taking part in the management of the crisis, given the involvement of a number of other institutions that are directly charged with these tasks.

The NCPHA has a scientific-expert participation in the Expert Council on Biocides (ECB) established by order of the Minister of Health. The Expert Council prepares authorisations for the placing on the market of biocidal products, including disinfectants. During the epidemic, the need for disinfectants in the country increased sharply and respectively the number of disinfectants considered by the Board increased manifold. They were assessed in the shortest possible time by the experts of the Toxicology Department at the Centre and authorisations for their placing on the market were prepared in a timely manner.

The active role of the NCPHA in tackling the pandemic process started at the beginning of the pandemic and has continued up to the present moment, especially intensifying in the autumn of 2020, when it became clear that the available resources in the system were insufficient. It should be noted that the experts of the NCPHA are simultaneously carrying out all ongoing tasks related to the activities of the Centre and no delay or postponement has been allowed. In total, more than 70 staff members of the NCPHA, which constitutes a significant strain on the available human resources, are involved in the various activities, which are grouped as follows:

Participation in the work of the Unified European Number 112

This task is in accordance with the Order No. RD-117/09.03.2020 of the Minister of Health and the additional recommendations of 13.03.2020 of the Deputy Prime Minister for Economic and Demographic Policy Mariana Nikolova regarding the activities of the administration in the operation of COVID-19. For its implementation, the Director of the NCPHA issued two orders approving the schedule of the 112 duty hours of the employees of the NCPHA—No. RD-172/19.03.2020 (28 employees) and No. RD-172/29.04.2020 (28 employees).

Epidemiological surveys through telephone interviews with infected persons and Participation in working groups for data entry of infected persons into the National Information System for Combating COVID-19

From the autumn of 2020, employees of NCPHA join the activities of the RHI-Sofia related to the epidemic spread of COVID-19 by conducting a telephone survey of persons infected with COVID-19. The Director of the NCPHA issued orders appointing the NCPHA staff (designated to carry out the activities of the different stages of the epidemiological survey of persons infected with COVID-19) to support the activities of the RHI-Sofia related to the epidemic spread of COVID-19, in accordance with the requirements and guidelines of the experts of the RHI-Sofia:

- No. RD-422/04.11.2020 (40 employees – 16 for conducting the epidemiological survey of contagious persons, 22 for entering the data from the epidemiological survey, two employees for the logistics team);

- No. RD-451/25.11.2020 (6 additional employees);
- No. RD-460/30.11.2020 (31 employees – 15 for conducting the epidemiological survey of contagious persons, 21 for entering the data from the epidemiological survey, 1 employee for the logistics team);
- No. RD-471/030.12.2020 (31 employees – 15 for conducting the epidemiological survey of contagious persons, 15 for entering the data from the epidemiological survey, 1 employee for the logistics team);
- No. RD-503/17.12.2020 (13 employees – 8 for conducting the epidemiological survey of contagious persons, 5 for entering the data from the epidemiological survey);
- No. RD-69/05.02.2021 (11 employees – 10 for conducting the epidemiological survey of contagious persons, 1 employee for the logistics team);
- No. RD-199/10.05.2021 (31 employees – 15 for conducting the epidemiological survey of contagious persons, 21 for entering the data from the epidemiological survey, 1 employee for the logistics team);
- No. RD-76/10.02.2021 (supplements the previous order with 2 employees);
- No. RD-138/23.03.2021 (12 employees for conducting the epidemiological survey of contagious persons);
- No. RD-199/10.05.2021 (13 employees – 11 for conducting the epidemiological survey of contagious persons, 2 employees for the logistics team).

Activities under Project BG 05M9OR001-1.099-0001 'Supporting health care workers in the face of public health threats', with beneficiary MoH, under Orders No. RD-476/04.12.2020 and RD-58/03.02.2021, by aggregating and entering data on the frontline experts submitted by the hospitals in the country

Twenty-six NCPHA employees have participated during the period December 2020 to April 2021. Data were entered for 222 facilities for October 2020, 203 facilities for November 2020 and 213 facilities for December 2020.

Activities in support of call centre activities related to the electronic vaccination register
According to Letter No. 829/17.03.2021 from the Deputy Minister of Health, the employees of the NCPHA are included in the activities of the so-called call centre, for answering phone calls from citizens and receiving signals about problems found in the operation of the electronic vaccination register. For this purpose, the Director of the NCPHA issued two orders specifying a list of NCPHA employees to work in the call centre— No. RD-149/02.04.2021 (8 employees) and No. RD-247/31.05.2020 (3 employees in addition to the previous list).

Analysis of the activities of the National Health Insurance Fund (NHIF)

It should be noted that a detailed analysis of the activities of the NHIF requires a longer period of research and data collection on the activities of this institution, as its decisions are directly dependent on the decisions of the government. One of the most serious shortcomings in the management of the crisis is the insufficient testing of citizens in order to provide insight into the actual spread of the virus. A tremendous policy mistake is the failure to accept PCR testing for COVID-19 by the state or through the NHIF. This leads to a strain on the budgets of individual

citizens on the one hand, and on the other, to a lack of adequate information on the spread of the virus.

The amounts disbursed for COVID-19 testing have been reviewed for the purposes of this report. Table 3 shows that the distribution of the amounts is extremely uneven across the country, both geographically and temporally. Territorially, there are districts in the country where not a single test has been paid by the NHIF and others where the amounts are in the millions. The districts where not a single PCR test was paid for during the monitoring period were Dobrich, Lovech and Pernik. In Haskovo and Sofia-region tests were paid only in the last two months of the period—March and April 2021. It is noteworthy that the only district where the payment of tests started already at the beginning of the observation period—in April 2020—is Plovdiv. This is probably related to the decision on an epidemiological survey of Plovdiv citizens. All remaining districts are included at the earliest in May (only four of them – Varna, Sofia-city, St. Zagora and Razgrad). In June, four more districts are included, with the number gradually increasing to reach full inclusion of all districts except the three mentioned above in April 2021. A total of BGN 18,439,860 has been paid over the entire period. The highest number of tests were paid in Sofia city – BGN 7,872,900, followed by Burgas – BGN 2,352,000, Plovdiv – BGN 1,879,860, and Varna – BGN 1,248,000. The highest number of tests were paid in March 2021 – BGN 4,674,960. (Table 3)

Table 3

Amounts paid by the NHIF for tests that prove COVID-19 infection – (as per Ordinance No. 9 of 10.12.2019 on the determination of the package of health activities guaranteed by the budget of the National Health Insurance Fund – Highly Specialised Medical Activity "Polymerase chain reaction for the proof of COVID-19"), by Regional Health Insurance Fund (RHIF) that paid for the tests and by month of performing the test

(in BGN)

No.	RHIF	Month and year of the tests													
		04'2020	05'2020	06'2020	07'2020	08'2020	09'2020	10'2020	11'2020	12'2020	01'2021	02'2021	03'2021	04'2021	Total by district
1	Blagoevgrad	0	0	0	16 800	30 060	34 320	81 240	145 380	84 480	28 920	46 920	137 760	93 960	699 840
2	Burgas	0	0	24 480	41 160	57 720	90 180	118 080	160 560	480 480	145 740	218 640	649 260	365 700	2 352 000
3	Varna	0	8 700	34 980	96 540	114 780	82 140	113 760	118 500	180 420	56 640	60 780	225 180	155 580	1 248 000
4	Veliko Tarnovo	0	0	0	0	0	0	4 140	30 720	82 440	21 300	26 880	118 980	91 020	375 480
5	Vidin	0	0	0	0	0	0	0	0	300	5 820	6 660	19 800	18 600	51 180
6	Vratsa	0	0	0	7 200	6 840	16 680	47 820	81 780	51 720	16 620	36 420	85 260	39 660	390 000
7	Gabrovo	0	0	0	0	0	0	22 380	72 360	33 780	6 840	14 640	18 060	13 140	181 200
8	Dobrich	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	Kardzhali	0	0	1 020	420	3 480	5 520	4 080	5 100	10 440	4 440	3 540	12 900	15 000	65 940
10	Kyustendil	0	0	0	0	0	0	0	0	0	7 080	37 380	52 200	22 860	119 520
11	Lovech	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	Montana	0	0	0	0	0	0	10 440	50 280	43 080	11 760	15 840	63 900	40 560	235 860
13	Pazardzhik	0	0	0	360	4 800	4 200	6 900	7 740	29 220	7 020	10 200	34 740	16 560	121 740
14	Pernik	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	Pleven	0	0	6 960	12 540	8 100	2 220	13 740	12 960	53 640	24 180	39 120	90 900	32 940	297 300
16	Plovdiv	2 880	16 020	21 120	32 640	82 440	58 140	130 440	161 520	250 320	152 100	177 660	450 180	344 400	1 879 860
17	Razgrad	0	3 360	8 580	6 420	4 020	9 060	29 100	8 520	19 980	6 660	1 680	14 580	8 760	120 720
18	Ruse	0	0	1 020	15 660	22 800	15 420	27 840	32 220	101 400	40 980	46 260	155 580	119 400	578 580
19	Silistra	0	0	0	0	0	0	18 120	28 920	28 920	10 680	13 740	64 200	26 940	191 520
20	Sliven	0	0	0	0	0	0	0	1 140	29 700	15 240	24 780	55 200	42 300	168 360
21	Smolyan	0	0	0	0	0	0	0	9 120	17 940	4 860	5 940	32 280	20 160	90 300
22	Sofia-city	0	4 620	111 180	194 760	116 340	158 760	381 360	549 300	1 503 540	557 880	818 460	2 107 440	1 369 260	7 872 900
23	Sofia-region	0	0	0	0	0	0	0	0	0	0	0	10 020	19 380	29 400
24	Stara Zagora	0	2 040	15 180	18 780	37 500	48 120	66 540	149 820	148 200	32 100	38 160	110 880	86 640	753 960
25	Targovishte	0	0	0	0	0	0	0	0	0	0	0	720	6 120	6 840
26	Haskovo	0	0	0	840	1 620	6 240	10 620	57 360	63 360	22 380	38 580	60 060	33 000	294 060
27	Shumen	0	0	0	0	0	0	0	16 440	50 880	21 960	39 660	81 840	34 740	245 520
28	Yambol	0	0	0	0	0	0	0	0	17 100	5 580	8 820	23 040	15 240	69 780
	Total by month	2 880	34 740	224 520	444 120	490 500	531 000	1 086 600	1 699 740	3 281 340	1 206 780	1 730 760	4 674 960	3 031 920	**18 439 860**

Source: NHIF

The analysis of these payments shows that the disbursement of the tests did not follow the needs caused by the pandemic and the dynamics of the number of infected during the period. For example, fewer tests were paid out in the period September-December than in April 2021, when the pandemic saw a decline in infections. It is more likely that the gradual increase in the number of laboratories determines the increased payments from the NHIF. (Figure 79)

Fig. 79

Source: NHIF

One very significant milestone in the NHIF activity is the price adjustment of three pathways and two procedures, which are used to account for treatment activity in relation to COVID-19, only occurs on 01/11/2020, that is, at the peak of morbidity and mortality from COVID-19. This fact again illustrates the slow response of the crisis management regarding the funding of pandemic related activities. It is unlikely that the NHIF on its own can make this adjustment and sign the annex to the NFA, which is the legal procedure for such an adjustment—this requires the will of the Ministry of Health, respectively of the Supervisory Board of the NHIF, which plays a key role in decision-making by the Treasury and the two professional organisations of doctors and dentists who participate in the framework agreement.

Part 9

Analysis and evaluation of the effect of the applied general counter-epidemic measures

The National Plan for Pandemic Preparedness of the Republic of Bulgaria aims to limit morbidity, reduce mortality and provide optimal conditions to treat the sick and maintain the functioning of essential sectors of public life such as healthcare, security, transport, etc.

By Decision of 13.03.2020, the National Assembly of the Republic of Bulgaria declared a state of emergency regarding the spread of COVID-19, and as of 14.05.2020 an epidemic emergency situation. Depending on the development of the epidemic situation, counter-epidemic measures are gradually introduced in accordance with the recommendations of the WHO and European structures.

Counter-epidemic measures related to entry into the territory of the country

The measures regarding the implementation of border health controls are established by Orders, amended and supplemented during the period under review March 2020 – 31 May 2021 and have the following chronology:

On 15.03.2020, counter-epidemic measures are introduced to limit the entry and spread of the COVID-19 pandemic on the territory of the Republic of Bulgaria and temporary border health control units were established. As of 18.03.2020 a ban is imposed on the entry into the territory of the country of persons from a number of countries in Europe and Asia, with the exception of Bulgarian citizens, members of their families and persons with permanent and long-term residence status on the territory of Bulgaria, as well as their family members. Arrivals from the countries listed in the orders are placed under a mandatory 14-day quarantine in their homes or other accommodation as prescribed by the border health authorities. There are also provisions for drivers of international heavy goods vehicles, which are different for Bulgarian and foreign nationals, especially from countries that are banned from entering the country. Transit through the country is regulated.

As of 26.03.2020 a ban on entry into the country is introduced for citizens of countries with registered cases of COVID-19. In accordance with the epidemic situation and the extent of the spread of the infection in different parts of the world, the measures concerning border control are actively changing, with the initial restrictions being extended and the list of countries from which entry into Bulgaria is prohibited growing. At the same time, a variety of cases involving citizens of different countries, as well as diplomatic, infrastructural, as well as social issues and difficulties are emerging, which requires a dynamic approach and an actualisation of the counter-epidemic measures. In mid-May, those working in tourism and those supplying medical devices, apparatus and personal protective equipment are added to the exceptions to the entry ban.

From 22.05.2020, in line with the epidemic situation, the measures are gradually eased, allowing the entry into Bulgaria of citizens of EU Member States and Schengen countries, and gradually the list of countries increases. All persons, with the exception of specifically mentioned groups, are placed under a 14-day quarantine, while as of 18.06.2020 nationals of certain countries are no longer subject to quarantine.

As of 15.07.2020, those providing a negative result from a polymerase chain reaction (PCR) test performed within 72 hours prior to arrival in Bulgaria, are exempt from quarantine. Measures are significantly relaxed in August and September 2020, with the requirement for nationals of dozens

of countries to comply with quarantine or provide proof of a negative PCR test result being lifted.

As of 01.10.2020, a temporary ban on entry into the territory of the Republic of Bulgaria of all persons, regardless of their citizenship, through all border crossing points, by any means of transport, is reintroduced while maintaining the above-described exceptions and conditions.

As of 01.12.2020, the counter-epidemic measures are considerably tightened, including border controls. The exemptions for entering the country are maintained, but the quarantine is reduced to 10 days. From 20.12.2020, a mandatory 10-day quarantine is introduced for arrivals from the United Kingdom and Northern Ireland. From 24.12.2020 to 31.01.2021, persons arriving in the country by air are also subject to a rapid antigen test for COVID-19 by border health authorities. In case of a negative result, a quarantine order for 10 days is issued, whereas in case of a positive result, a quarantine order for 14 days is issued. Exceptions are made for officials and members of their delegations who present proof of a negative PCR test result within 48 hours before entering the country, drivers of goods vehicles, crew members of vessels and aircraft, in case they do not leave them, as well as for those in transit through the territory of the country.

As of 01.01.2021, persons who are allowed to enter the country are required to present a document upon arrival showing a negative PCR test result for COVID-19 conducted up to 72 hours prior to entering the country, or they are quarantined for a 10-day period. During the period 29.01-30.04.2021 the ban on entry into Bulgaria from all countries—beyond those specifically mentioned in the orders—is extended for all persons except those belonging to certain categories. Citizens of the United Kingdom of Great Britain and Northern Ireland are allowed to re-enter the country. For the remaining persons allowed entry, the condition of a negative PCR test result or compliance with a 10-day quarantine is maintained.

From 02.02.2021 the PCR test does not need to be provided by drivers of heavy trucks, crews of vessels and border workers, and from 17.02.2021 to those are included drivers of buses performing regular international courses, and pupils and students from countries with a common border with Bulgaria who travel daily or at least once a week.

During the period 13.03-30.04.2021, a quarantine of 10 days is added for all persons allowed entry into the country and arriving from countries and territories in Africa. An exception to the 10-day quarantine is granted during the period 01-30.04.2021 for persons arriving from certain countries in Africa after providing a negative PCR test result.

In May 2021 the entry into the territory of Bulgaria of persons arriving from India, Bangladesh, Brazil, countries and territories in Africa is temporarily banned, and the arrivals from these countries of Bulgarian citizens, members of their families and persons with permanent and long-term residence status on the territory of Bulgaria and their family members are quarantined for a period of 10 days. Persons from all other countries are allowed to enter after providing proof of completion of vaccination and expiry of a 14-day period after the last dose; proof of COVID-19 prevalence for the period from the 15th to the 180th day from the date of the test; and a negative PCR or rapid antigen test.

Counter-epidemic measures in the workplace

In the immediate aftermath of the declaration of a state of emergency on 13.03.2020 with regard to the spread of COVID-19, the Minister of Health issues an order with measures to contain the spread of COVID-19 in the workplace, which is replaced by a new order upon the transition to an epidemic emergency.

The orders are mandatory for compliance by all employers. They include the obligation, depending on the specificities and possibilities of the work activity concerned, to introduce teleworking and,

where this is not possible, employers must ensure the implementation of enhanced counter-epidemic measures in the work premises, the arrangement of a filter to exclude persons with signs of acute infectious diseases, disinfection and ventilation, the assurance of physical distance, the provision of personal protective equipment to personnel (depending on the specifics of the work and the workplace risk assessment), wearing a disposable or reusable face mask or other means of covering the nose and mouth in enclosed public places, providing instructions to the personnel, etc.

Specific measures are in place for persons with professions that put them in physical contact with people and are at high risk of infection with COVID-19. These include those working in health care, nursing homes, as well as individuals working in food supply and retail, public institutions, the utility services, public transport, etc. Among the technical measures to limit the risk of COVID-19 infection in the workplace are: providing adequate workplace protection such as screens, barriers, access control, thermometry of outsiders, etc.; providing disinfectants and detergents, including antiseptics for skin and surfaces; providing appropriate PPE, such as upper respiratory protection masks/respirators, helmets, protective gloves, work clothing and special storage containers for used PPE and hygiene materials.

Information on anti-epidemic measures, including those related to the workplace, is available on the websites of the Ministry of Health, the COVID- 19 Unified Information Portal and the National Centre for Infectious and Parasitic Diseases. The NCPHA, in its capacity as the WHO Collaborating Centre for Occupational Health, disseminated and published on its website the WHO recommendations for preparing enterprises for the pandemic as early as 04.03.2020, a few days before the first detected cases of COVID-19 in the country on 08.03.2020. Subsequently, materials were translated, adapted and published on issues related to the prevention of COVID-19 infection and ensuring health and safety at workplaces in an epidemic setting, health protection of health workers, their rights and obligations, organization of workplaces and activities in hospital care; rational use of PPE, rules for personal hygiene and disinfection, risk assessment, management of exposure of health workers in the context of COVID-19, etc. Information on counter-epidemic measures was also published on the websites of RHI, occupational health services, NGOs, etc.

The measures applied in the country are in line with the later published EU guidelines "COVID-19: Back to the workplace - Adapting workplaces and protecting workers", translated and available on the website of the Executive Agency General Labour Inspectorate (EA GLI). Additional measures include risk assessment, special attention to the employees who are at high risk, including the elderly and those with chronic diseases (including hypertension, lung or heart problems, diabetes, etc.), revision of work procedures to minimize the necessary contacts inherent in the activity, both with outsiders and between workers, revision of the list of workplaces and types of PPE for protection against biological risks, and, if necessary, the introduction of shift work for staff. The challenges of adapting workplaces to a pandemic are immense given the diversity of activities and their organisation. Good practices to limit the risk of contamination for different sectors of activity are published on the website of the EA GLI.

In 2019 and 2020, two amendments were made to Directive 2000/54/EC to improve the protection of workers from biological risks at work, including COVID-19. Directive (EU) 2019/1833 and Directive (EU) 2020/739 were transposed into national law in a timely manner by Ordinance amending and supplementing Ordinance No. 4 of 2002, published in the State Gazette on 24 November 2020. Annex 1 of the Ordinance reflects the amendments to Annex III of Directive 2000/54/EC introduced by Directive (EU) 2019/1833 and Directive (EU) 2020/739, which results in the addition of a number of biological agents, including the coronavirus associated with severe

acute respiratory syndrome (SARS coronavirus), the Middle East respiratory syndrome coronavirus (MERS virus), and the new SARS-CoV-2 virus.

On 5 November 2020, the NCPHA, together with the Ministry of Labour and Social Policy (MLSP) and the support of the European Agency for Safety and Health at Work (EU-OSHA), held a remote workshop for specialists on the subject "Healthy Workplaces: Protecting the Health of Workers in the Context of a COVID-19 Pandemic", at which were announced the changes in legislation, the challenges of ensuring health and safety in a pandemic, the reassessment and control of health risk in relation to COVID-19, high-risk activities, vulnerable groups of workers, the organisation of telework in pandemic conditions, etc. The materials are published in the journal 'Health and Safety at Work', issue 2020, available on the NCPHA website with open access.

The EA GLI informed the employers about the COVID-19 risk assessment tool developed by the EU-OSHA, which was translated into Bulgarian and adapted to the Bulgarian legislation. The tool does not cover healthcare establishments for which specific regulations and instructions of the health authorities are available.

The Ministry of Economy designed measures to support enterprises through the Grant Scheme "Adaptation of the activities of SME's in the context of COVID-19". Under this scheme, expenses are eligible for the provision of collective protective equipment, sanitation and disinfection equipment, including the installation of automatic dispensers, reorganization and adaptation of work processes, air conditioning and ventilation to minimize the risk of air circulation, provision of remote working facilities through remote access hardware/software, etc.

Following the declaration of the COVID-19 pandemic and the state of emergency introduced in the country on 13.03.2020, which subsequently turned into an epidemic emergency, the EA GLI carried out inspections in relation to the measures taken by employers to limit and reduce the risk of the spread of infection in the workplaces. In 2020, 46% of all the Agency's inspections (37,145) were specifically aimed at identifying employer actions to implement the counter-epidemic measures and actions related to the state of emergency/the epidemic outbreak. These inspections found that employers generally fulfilled their obligations under labour law to protect the life and health of workers. In only 3% of the establishments inspected personnel were not aware of the measures taken in the establishment to protect themselves from COVID-19. In about 7% of the inspections, it was found that signs and information materials regarding the basic measures to prevent infection were not posted and no prior information on the health status of workers was collected. In 2020, the EA GLI carried out joint inspections—within its powers—with other control bodies, including control of compliance with counter-epidemic measures against COVID-19. Inspections were carried out in response to signals from the RHI concerning compliance with counter-epidemic measures at workplaces. In 2021, the EA GLI continued carrying out inspections related to compliance with counter-epidemic measures.

Counter-epidemic measures introduced on the territory of the country

1. *Restrictions on the gathering of a maximum number of persons in public places*

The measure is implemented between 11.03.2020 and 05.05.2021, and is permanent after November 2020 in terms of the requirements for the gathering of a maximum number of persons. Variations occur between May-October 2020, with no more than 10 to 30 persons allowed indoors and outdoors; occupancy of 30% to 50% of total seating capacity indoors and 50% outdoors and no more than 1 person per 4 square metres is allowed. For indoor and outdoor night-time entertainment establishments, an occupancy rate of no more than one person per square metre of the total seating capacity is allowed.

2. Requirements for keeping physical distance

The measure is implemented in the period 11.03.2020-31.05.2021, and has a permanent character without significant changes in its implementation and requirements in accordance with the orders of the Ministry of Health, which introduce it.

3. Restrictions on in-person attendance in Higher Education

At the beginning of the pandemic, it is recommended to suspend all educational activities in universities. From May to August 2020, learning practices and internships are allowed when they cannot be carried out remotely in an electronic environment and/or have an imminent in-person presence, provided that all counter-epidemic measures are respected. In September and October 2020, in-person activities in higher education establishments are allowed, in accordance with the requirements of the respective establishment while respecting the counter-epidemic measures, and where possible the learning process is also conducted remotely through an electronic platform. In the period from November 2020 to May 2021, in-person teaching in higher education institutions is suspended, with the exception of practical exercises, which cannot be carried out remotely through an electronic platform, as well as state examinations for the acquisition of a specialisation in the healthcare system, in strict compliance with infection prevention and control measures.

4. Restrictions on in-person attendance in primary and secondary education

From March 2020, school activities are suspended. From May to August 2020, teaching practices and internships are allowed when it is impossible to carry out these activities remotely through an electronic platform and/or with an imminent physical presence while complying with all counter-epidemic measures. With effect from 01.09.2020, in-person teaching is reinstated. As of 12.11.2020, attendance is suspended in districts with a 14-day morbidity rate of more than 119.9 per 100,000 population and 15% absenteeism due to COVID-19 symptoms. As of 27.11.2020, in-person classes are discontinued and the transition is made to distance education. From 15.01.2021 it is allowed to conduct in person equivalence exams in the cases of the transfer of a pupil, exams for determining the term grade of a subject or a module, exams for determining the annual grade of a pupil in an independent form of education, exams for determining the annual grade of a pupil in a part-time form of education, state exams for acquiring a degree of professional qualification on the theory or practice of the profession, and individual activities—individual classes, consultations, individual written or practical tests for ongoing assessment in cases where it is objectively impossible to conduct them remotely through an electronic platform, individual practical classes and practical classes at an individual workplace in an enterprise or on the territory of the school concerned, regional and municipal rounds of Olympiads and competitions where they cannot be conducted remotely through an electronic platform. From 4.02.2021, an in-person study schedule is introduced for students in grades 5 through 12. From 15.02.2021, attendance classes are allowed in classes which are the only classes in the respective grade of the school. From 22.03.2021 to 11.04.2021, attendance is again suspended. From 12.04.2021 to 31.05.2021, attendance is resumed for pupils in special schools, for pupils with sensory impairments in merged classes and in classes which are the only classes in the grade of the school concerned, while for the remaining pupils the classes are held as per schedule. Outside of the timetable, attendance at practice examinations, practical exercises and Olympiads is permitted. Attendance is restored from 31.05.2021.

5. Restrictions on in-person attendance in elementary education

As of 06.03.2020, educational activities in elementary schools are suspended, with the exception of activities to support and assist personal development. From 01.09.2020, in-person classes are resumed. From 27.11.2020, in-person classes are suspended and resume from 04.01.2020. From 22.03.2021 to 12.04.2021, classes are suspended again.

6. Suspension of visits to nurseries and kindergartens

As of 08.03.2020, the attendance of kindergartens and nurseries in the districts of Gabrovo and Pleven is suspended, and from 29.03.2020 to 21.05.2020 the measure came into force for the entire country. From 27.11.2020, kindergartens and nurseries are suspended again and from 4.01.2021 they are resumed. From 22.03.2021 to 05.04.2021 is the third period when visits to kindergartens and nurseries are suspended.

7. Introduced remote form of work/teleworking

The measure is implemented in the period March 2020-May 2021 with no significant changes under the MoH orders that introduce it. The measure is also addressed under "Counter-epidemic measures in the workplace".

8. Introduced counter-epidemic measures at workplaces

The measure is implemented between March 2020 and May 2021 without significant changes, with renewal orders issued periodically. The employers organise the implementation of enhanced counter-epidemic measures in workplaces, including filtering, disinfection and ventilation, instruction on personal hygiene for personnel and the non-admission of employees or outsiders with signs of acute communicable diseases. The measures and their chronology are discussed in more detail under "Counter-epidemic measures in the workplace".

9. Requirement of using protective face masks in open public places

The measure is implemented partially in the period 30.03.2020-31.05.2021, and it is non-permanent with most of the time of a recommendatory nature. On 31.03.2020 it is repealed by Order No. RD-01-169/31.03.2020 and came into force again on 11.04.2020. It is recommended mainly in crowded situations and where it is not possible to ensure physical distance. The restrictive measure targets all age groups due to ‘rejuvenation’ of the infection and affecting persons of all ages.

10. Requirement of using protective face masks in indoor public places

The measure applies for the period 30.03.2020-31.05.2021 and is stable over time with minor variations in the months of March and April 2020. It affects all persons who are on public transport, in medical and health facilities and in enclosed public places where there is a crowding and the recommended physical distance cannot be ensured.

11. Suspension of activities at sport facilities

The measure applies for the period 13.03.2020 - 30.04.2021, whereby for the period from May 2020 to February 2021 certain sporting activities are partially permitted subject to certain conditions. For the months of March and April 2021, the measure applies without affecting athletes registered with the sports federations and sports competitions are held without an audience. During the month of May 2021, the measure is suspended by Order No. RD-01-355/18.05.2021, allowing sports competitions to be held with an audience, provided that no more than 50% of the seats are occupied, a physical distance of at least 1.5m is maintained and protective face masks are worn.

12. Suspension of the activities of drinking and food establishments

The measure applies for the period 13.03.2020-30.04.2021, but is subject to numerous changes. As of 04.05.2020, the use of outdoor commercial areas (gardens, terraces, etc.) by restaurants, fast-food outlets, drinking establishments and coffee shops is allowed, provided that counter-epidemic measures are respected. Discotheques, piano bars and nightclubs operate under certain conditions until November 2020, after which they are suspended for a specified period. In December 2020, Order No. RD-01-718/18.12.2020 allows only restaurants to operate on the territory of the places of accommodation, at 50% of their capacity and with limited opening hours. As of May 2021, there

are no restrictive measures for drinking and eating establishments, except that they operate in compliance with given conditions.

13. Suspension of the activities of retail outlets for non-food goods

The measure applies for the period 13.03.2020-31.05.2021 and is unstable over time. From 13.03.2020 to 14.06.2020 it is forbidden to visit shopping centres of the shopping mall type. During the following months, all commercial establishments operate in compliance with certain counter-epidemic measures, keeping distance and wearing protective masks. Order No. RD-01-677/25.11.2020 suspends again the visits to shopping malls and stays in force until 01.02.2021. Order No. RD-01-173/18.03.2021 imposes strict restrictive measures on shops with a net sales area of more than 300 square metres offering non-food goods.

14. Suspension of mass events (cultural, entertainment, educational, sports, etc.)

The measure is applied in accordance with the complexity of the epidemiological situation. From March to May 2020, the conduct of all types of mass events, including sporting, cultural, entertainment and educational events, is suspended. From 14.05.2020 individual activities are allowed under certain conditions. By Order No. RD-01-452/04.08.2020, cultural and entertainment events are allowed to be organised if the seats are occupied up to 50% of their total capacity and subject to a physical distance of 1.5m. From December 2020 to April 2021, restrictive measures are reintroduced, with the exception of theatres, where seats are occupied up to 30% of their total capacity, distance is respected and safety masks must be worn. By Order No. RD-01-375/27.05.2021, the measure is repealed, allowing events to take place under certain conditions.

15. Suspension of prophylactic examinations, admissions and elective surgery, pediatric and women's consultations, and appointments in health facilities

The measure applies throughout the epidemic period from 13 March 2020 to 31 May 2021, with multiple changes between March 2020 and January 2021. In the period from 13.03.2020 to 20.04.2020, by Order No. RD-01-124/13.03.2020, item 7, the measure is introduced in full scope. After 21.04.2020, Order No. RD-01-225/20.04.2020 restores planned admission, children's and women's consultations and basic compulsory immunizations, but the restrictions related to organ transplants and appointments in all medical institutions remain in force. As of 01.09.2020 (Order No. RD-01-489/31.08.2020, item 9), appointments of terminal patients are allowed. Order No. RD-01-619/23.10.2020 again suspends elective admissions and elective surgery until 15.01.2021 (Order No. RD-01-20/15.01.2021, item 4). In the period 15.01.2021-31.05.2021, the measure in force remains the suspension of visits to medical establishments, with the exception of visits of patients in terminal stage.

16. Suspension of the use (or introduction of restrictions on the use) of urban parks and gardens

The measure is valid from 20.03.2020-27.04.2020. From 27.04.2020, by Order No. RD-01-239/26.04.2020, visits to urban parks and gardens are allowed under strict compliance with certain counter-epidemic measures. In May 2020 there are certain restrictions on the use of playgrounds and sports facilities in indoor public places. During the remaining period, from June 2020 to May 2021, no restrictions are imposed.

In Table 4, based on data from the MoH, the implementation of the counter-epidemic measures (marked 1-16) discussed above, including those related to the workplace (marked 7 and 8), is chronologically observed and reported in three conditional categories. In order to give a general outline of the action and nature of the counter-epidemic measures in place, the same information is presented in schematic form and summarised by month in Table 5. The scheme is conditional given the different dates of introduction and change of measures, and the overlap/co-operation of

more than one measure in different months/time periods.

Table. 4. Chronology of the implemented counter-epidemic measures, according to information from the Ministry of Health

	Counter-epidemic measures introduced by MoH orders, by month	**2020**										**2021**				
	Counter-epidemic measures	**March**	**April**	**May**	**June**	**July**	**August**	**September**	**October**	**November**	**December**	**January**	**February**	**March**	**April**	**May**
1	Restrictions on the gathering of a maximum number of persons in public places	Yes	Yes	Yes (from 14.05 to 26.05.2020)	No (for one day there is limit of 10 persons)	Yes, under certain conditions	Yes, under certain conditions	Yes, under certain conditions	Yes, under certain conditions	Yes	Yes	Yes	Yes	Yes	Yes	Yes (until 05.05.2021)
2	Requirements for keeping physical distance	Yes, for certain groups	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3	Restrictions on in-person attendance in Higher Education	Yes	Yes	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	No	No	Yes, with exceptions for certain professional fields	Yes, with exceptions for state examinations for certain professional fields	Yes, with exceptions for state examinations; from 15.01.2021 , exception for practice and practical examinations training	Yes, with exceptions for state and practice exams and practical training	Yes, with exceptions for state and practice exams and practical training	Yes, with exceptions for state and practice exams and practical training	Yes (until 19.05.2021)
4	Restrictions on in-person attendance in primary and secondary education	Yes	Yes	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	No	No	Yes, for high school. From 13.11.2021 in districts with a 14-day morbidity rate	Yes	Yes, from 15.01.2021 certain examinations and individual activities allowed	Yes, on an attendance schedule	Yes, until 22.03.2021 on schedule for in-person learning	Yes, until 12.04.2021	Yes, until 31.05.2021
5	Restrictions on in-person attendance in elementary education	Yes	Yes	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	No	No	No	Yes	Yes, until 04.01.2021	No	Yes, from 22.03.2021	Yes, until 12.04.2021	No
6	Suspension of visits to nurseries and kindergartens	Yes	Yes	Yes, until 21.05.2021	No	No	No	No	No	No	Yes	Yes, until 04.01.2021	No	Yes	Yes, until 05.04.2021	No

7	Introduced remote form of work/teleworking	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8	Introduced counter-epidemic measures at workplaces	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9	Requirement of using protective face masks in open public places	Yes, only for 30.03.2020	Yes, from 12.04.2020	Yes	Recommended	Recommended	Recommended	Recommended	Yes, from 22.10.2020 - in case of crowding and inability to keep physical distance of 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.	Yes, in case of crowding and inability to keep physical distance 1,5 m.
10	Requirement of using protective face masks in indoor public places	Yes, only for 30.03.2020	Yes, from 12.04.2020	Yes	Yes, mandatory in public transport, pharmacies and medical facilities. In other indoor public places where distance cannot be provided, it is recommended.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
11	Suspension of activities at sport facilities	Yes	Yes	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, certain activities are permitted subject to certain conditions	Yes, with certain exceptions	Yes, with certain exceptions	Yes, exemptions for registered athletes to the sports federations. Sports competitions - without audience.	Yes, exemptions for registered athletes to the sports federations. Sports competitions - without audience.	No, they work under certain conditions

12	Suspension of the activities of drinking and food establishments	Yes	Yes	Yes, from 04.05.2020. allowed in open areas, subject to certain conditions	Yes, they can work under certain conditions	No (discos, piano bars, nightclubs, etc. operate under certain conditions)	There are requirements for discos, piano-bars, night-clubs and similar establishments	There are requirements for discos, piano-bars, night-clubs and similar establishments	There are requirements for discos, piano-bars, night-clubs and similar establishments	Discotheques, piano bars, nightclubs and other similar establishments are suspended. Other eating and entertainment establishments operate under certain conditions.	Yes, from 18.12.2020 an exception is allowed for restaurants on the premises of accommodation under certain conditions	Yes, an exception is allowed for restaurants on the premises of accommodation, subject to certain conditions.	Yes, until 28.02.2021, an exception is allowed for restaurants on the premises of accommodation, subject to certain conditions. The rest from 26.02.2021 under certain conditions, excluding discos, piano-bars, night-clubs, etc. similar establishments	Yes, an exception is allowed for restaurants on the premises of accommodation, subject to certain conditions.	Yes, under certain conditions.	No, they work under certain conditions.
13	Suspension of the activities of retail outlets for non-food goods	Yes	Yes	Yes, until 18.05.2020 the shopping mall category.	No	No	No	No	No	No, they work under certain conditions	Yes, for shopping centres and malls.	Yes, for shopping centres and malls.	No	Yes	Yes, until 11.04.2021 – shops with a net sales area exceeding 300 sq. meters; until 15.04.2021 – shopping centres and malls.	No, they work under certain requirements.
14	Suspension of mass events (cultural, entertainment, educational, sports, etc.)	Yes	Yes	Yes, as of May 14, certain activities are allowed under certain conditions.	They take place under certain conditions.	They take place under certain conditions.	No, they are held under certain conditions.	No, they are held under certain conditions.	No, they are held under certain conditions.	No, they are held under certain conditions.	Yes	Yes, they are allowed. Museums and galleries work under certain conditions.	Yes, they are allowed under certain conditions.	Yes	Yes, after 12.04.2021 under certain conditions.	No, they work under certain conditions.

15	Suspension of prophylactic examinations, admissions and elective surgery, pediatric and women's consultations, and appointments in health facilities	Yes	Yes, there remain suspended appointments in medical facilities after April 20, 2020.	Yes, hospital appointments remain suspended.	Yes, hospital appointments remain suspended.	Yes, hospital appointments remain suspended.	Yes, hospital appointments remain suspended.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients. From 25.10.2021, elective admissions and elective surgery for certain conditions.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients. Elective admissions and elective surgery under certain conditions have been suspended.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients. Elective admissions and elective surgery under certain conditions have been suspended.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients.	Yes, hospital appointments remain suspended, with exceptions for appointments of terminal patients.
16	Suspension of the use (or introduction of restrictions on the use) of urban parks and gardens	Yes	Yes, from 27.04.2020 visits to city parks and gardens are allowed.	Yes - sports and children's playgrounds and indoor public facilities. From 01.05.2020 the requirement is removed for National Parks, mountains, etc.	No	No	No	No	No	No	No	No	No	No	No	No

Table.5. Scheme of action of the implemented anti-epidemic measures, according to chronological data provided by the Ministry of Health*

	Counter-epidemic measures introduced by orders of the Ministry of Health, by months	**2020**										**2021**				
	Counter-epidemic measures	**March**	**April**	**May**	**June**	**July**	**August**	**September**	**October**	**November**	**December**	**January**	**February**	**March**	**April**	**May**
1	Restrictions on the gathering of a maximum number of persons in public places															
2	Requirements for keeping physical distance															
3	Restrictions on in-person attendance in Higher Education															
4	Restrictions on in-person attendance in primary and secondary education															
5	Restrictions on in-person attendance in elementary education															
6	Suspension of visits to nurseries and kindergartens															
7	Introduced remote form of work/teleworking															
8	Introduced counter-epidemic measures at workplaces															
9	Requirement of using protective face masks in open public places															
10	Requirement of using protective face masks in indoor public places															
11	Suspension of activities at sport facilities															
12	Suspension of the activities of drinking and food establishments															
13	Suspension of the activities of retail outlets for non-food goods															
14	Suspension of mass events (cultural, entertainment, educational, sports, etc.)															
15	Suspension of prophylactic examinations, admissions and elective surgery, pediatric and women's consultations, and appointments in health facilities															
16	Suspension of the use (or introduction of restrictions on the use) of urban parks and gardens															

Yes

Yes, with conditions

No

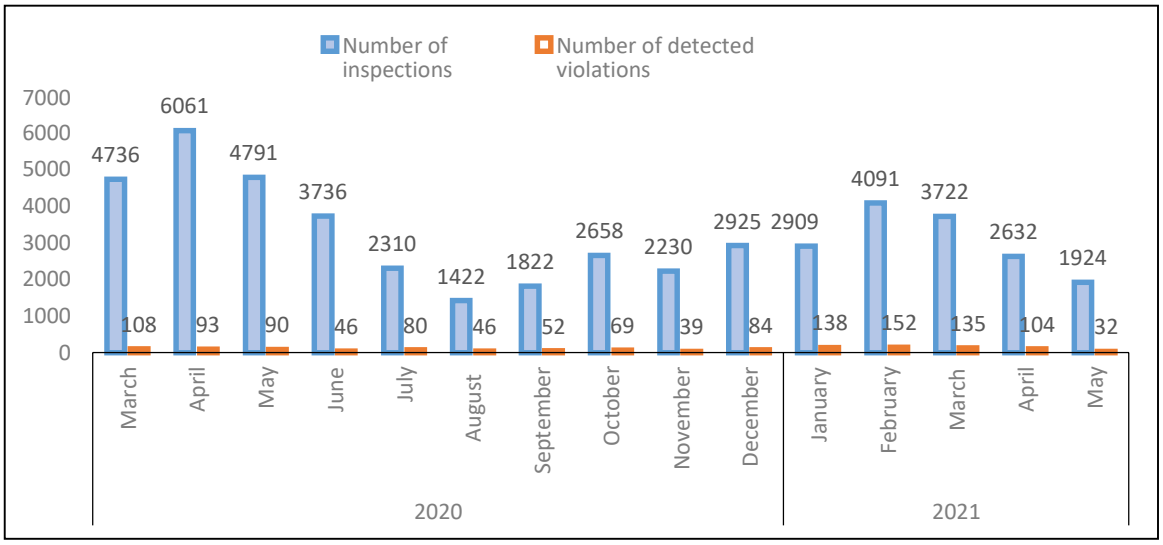
** The purpose of the figure presented is to give a general overview of the implemented counter-epidemic measures by month.*

Considering the State Health Surveillance (SHS) carried out by RHI's for compliance with the counter-epidemic measures against the spread of SARS-CoV-2 (COVID-19), for the period March 2020-May 2021, the number of inspections carried out and violations detected by the 27 RHI's in the country for two groups of measures are tracked by month.

1. *Suspension or restriction of the activities of drinking and food establishments, sports clubs and gyms, suspension of mass events*

Accordingly, the 27 RHI's have carried out a total of 47,969 inspections, with 1,268 violations detected. Figure 80 shows the distribution of inspections and infringements detected by month, with significant variation in the number of inspections. The most active SHS is observed in the periods April-May 2020 and February-March 2021. The lowest number of inspections were implemented in August and September 2020. The number of detected violations was lowest in May 2021 (32) and highest in February 2021 (152).

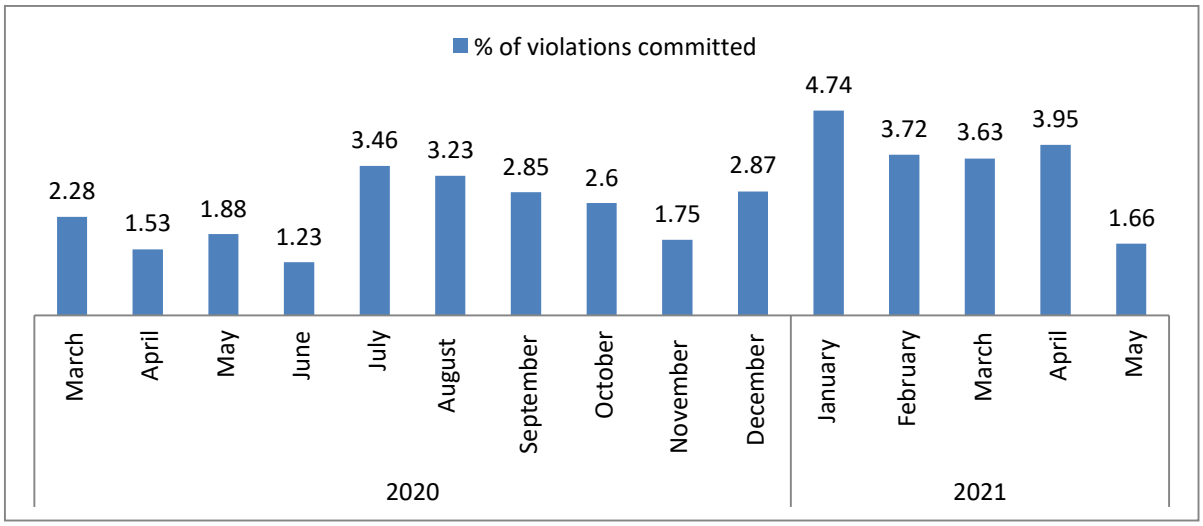
Fig. 80 Total number of inspections and violations detected by month in the period March 2020 - May 2021 regarding compliance with counter-epidemic measures: suspension or restriction of the activities of drinking and food establishments, sports clubs and gyms, suspension of mass events



Source: RHI

Figure 81 shows the number of infringements detected by month as a relative proportion (%) of the total number of inspections in the same months. The highest number of infringements occurs in the period January-April 2021 and the lowest proportion at the beginning of the state of emergency/epidemic emergency (March-June 2020).

Fig. 81 Violations detected by month as a relative proportion (%) of the total number of inspections in the same months for compliance with counter-epidemic measures: suspension or restriction of the activities of drinking and eating establishments, sports clubs and gyms, suspension of mass events

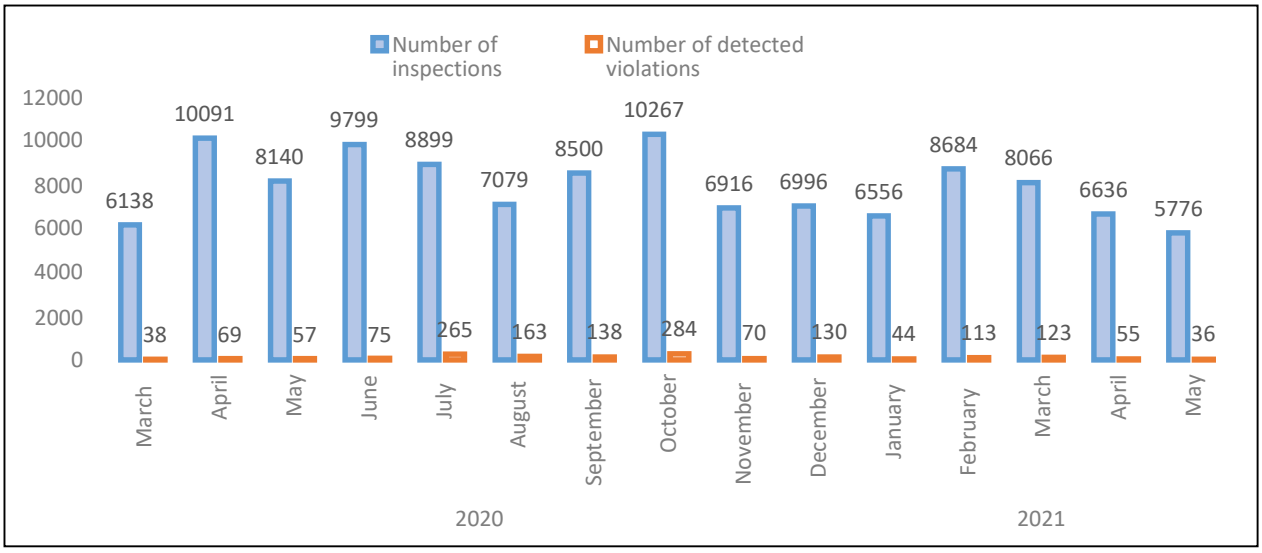


Source: RHI

2. *Use of protective face mask in indoor public places, commercial establishments, public means of transport, etc.*

The inspections carried out and the infringements detected under this measure are presented by month in Figure 82. For the period March 2020-May 2021, a total of 118,543 inspections were carried out by the 27 RHI's and 1,660 infringements were detected. Inspections have been carried out at a relatively constant rate over time, with the highest number of infringements found between July and October 2020.

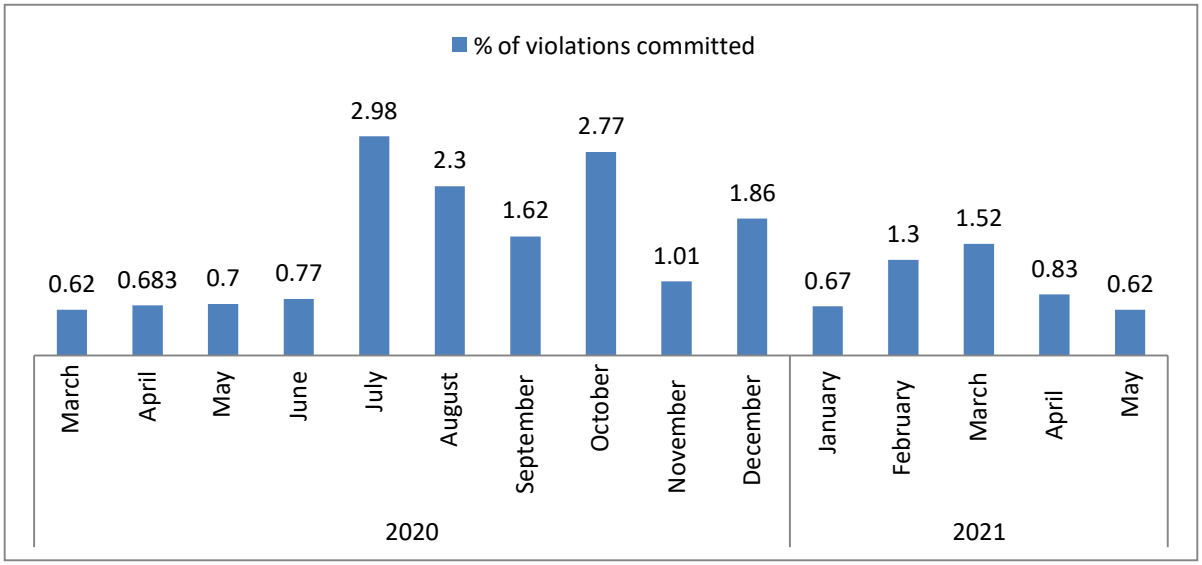
Fig. 82 Total number of inspections and violations detected by month in the period March 2020 - May 2021 regarding compliance with the counter-epidemic measure: use of face protection mask in indoor public places, commercial establishments, public transport, etc.



Source: RHI

Figure 83 shows the infringements detected by month as a relative share (%) of the total number of inspections in the same months for the measure under consideration. The highest number of infringements is recorded in July and October 2020, while the lowest proportion of infringements recorded by the RHI is recorded at the beginning and end of the monitoring period – March 2020 and May 2021.

Fig. 83 Violations detected by month as a relative share (%) of the total number of inspections in the same months for compliance with the counter-epidemic measure: use of protective face mask in indoor public places, commercial establishments, public transport, etc.



Source: RHI

Part 10

Analysis of the prevention activities related to COVID-19: vaccination plan, supply and provision of vaccines, and decisions of the National Vaccination Task Force

The National Vaccination Plan against COVID-19 (NVP) was adopted by Decision No. 896 of the Council of Ministers of the Republic of Bulgaria on 07.12.2020. It was developed by a working group under the order of the Minister of Health with the participation of experts from the Ministry of Health, regional health inspectorates, the Executive Agency for Medicines, leading medical specialists, the Bulgarian Medical Association, the Bulgarian Dental Association, the Bulgarian Pharmaceutical Association and others. It is pointed out that the WHO guidelines, plans of EU member states (Italy, France, Germany), England and individual states (Illinois) of the USA were used for its establishment, while considering the peculiarities of the Bulgarian healthcare, territory, infrastructure, etc. It is intended to be a dynamic document, equipped for adequate adaptation to the specific situation.

To coordinate and control the implementation of the NVP, a National Vaccination Task Force (NVTF) was established by the same decision, while also defining its composition. Subsequent amendments and additions to the Plan have been made by Decisions of the Council of Ministers published on the COVID-19 Unified Information Portal.

An important stage in addressing the COVID-19 crisis is the development and implementation of a vaccine. The aim is to counteract the spread of the virus, reduce the potential health consequences, achieve immunity in a large proportion of the population and therefore also protect those who cannot be immunised and are at risk of a more severe course and complications. In order to be administered, vaccines must be authorised to be placed on the market in the European Union. If sufficient data are available on the quality, safety and efficacy of any vaccine developed, the European Commission grants authorisation for use in all EU Member States. The supply of vaccines against COVID-19 is ensured through an Agreement approved by Decision № 491 of the Council of Ministers of 2020 and ratified by the Law on Ratification of the Agreement (issued in the State Newspaper No. 71 of 11.08.2020).

The NVP presents key components for vaccination against COVID-19 and describes the process of provision, implementation, monitoring and evaluation of vaccination of the population in Bulgaria. It shows that the order of coverage with the first vaccine deliveries is envisaged in several phases according to the risk of infection and the need to maintain critical pillars for the functioning of society:

Phase I: Medical staff of outpatient and inpatient care facilities, health care professionals, dentists, pharmacists, assistant pharmacists and other supporting staff.

Phase II: Users and staff of social institutions, educational specialists and personnel of mink farms.

Phase III: Employees involved in maintaining the functioning of activities essential to public life.

Phase IV: Elderly persons aged 65 years and older and persons with concomitant chronic diseases due to the more severe course of the disease and the higher risk of developing complications and of mortality, including immunocompromised persons or persons with secondary immune deficiencies.

Phase V: Vulnerable population groups due to the high epidemiological risk of infection associated with their living conditions and lifestyles.

The plan also stipulates that the delivery of the COVID-19 vaccine to be carried out by dividing the country into six regions, each comprising several districts. The organisation and conduct of vaccinations should be in accordance with the delivery schedule, the number of persons to be vaccinated and the specific characteristics regarding their transport and storage.

Another aspect that is addressed in the NVP against COVID-19 is the need to conduct a communication campaign to ensure transparency in the implementation of the Plan and the provision (through various forms) of clear information to different groups of the society on the importance and benefits of vaccination for the formation of both individual and collective immunity, and the protection of population groups that are not subject to immunization given the presence of concomitant diseases or medical counter-indications. Crucial to the management and adaptation of the vaccination process is the monitoring of vaccine coverage at regional and national levels, an important tool for which has been the upgrade of the national COVID-19 information system with a vaccination module. The commitment to regular reporting to the relevant EU and WHO specialised structures overseeing the process is also highlighted.

Subsequently, and with regard to the implementation of the NVP against COVID-19 in the Republic of Bulgaria, a number of orders of the Minister of Health related to the organization of the immunization campaign were issued.

Order No. RD-01-726 of 23.12.2021 on the organization of the immunization campaign against COVID-19 is followed by a number of amendments/additions. According to the order, the campaign starts on 27.12.2020 on the territory of the entire country. It shall be organised at regional level by the RHI's. The immunizations are carried out by doctors in hospital and outpatient medical care facilities, RHI; by doctors in specialized bodies of the Ministry of Interior and the Ministry of Defence, as well as mobile immunization teams set up for this purpose. It is stipulated that, if necessary, medical specialists from emergency medical care centres and the health cabinets in kindergartens and schools or from other medical institutions may join the teams. Priority shall begin with coverage of persons in the target groups identified within phases I-V of the NVP, as immunization against COVID-19 is recommended and free of charge, and is given at will. The registration of administered immunizations is in accordance with the Regulation No. 15/2005 on immunizations in the Republic of Bulgaria and in an electronic immunization registry maintained as a module of the National Information System to combat COVID-19.

Order No. RD-01-92 of 11.02.2021 and its amendments include: Annex No. 1, which designates 376 medical institutions and RHI's by district in which to open temporary immunization units; the participation of all general practitioners to vaccinate willing persons.

Order No. RD-01-171 of 17.03.2021 determines the locations for requesting vaccination—with a GP, at a temporary immunization unit listed in Annex 1 or through the web-based platform 'COVID-19 Registration for vaccination', whereas in relation to the latter, Annex 2 indicates the temporary immunization units that operate with the platform.

Order RD-01-202 of 02.04.2021 specifies certain additions, including the entry of data on the day of administration of the relevant vaccine through the medical software of GP's or through

https://imunno.his.bg/login of the temporary immunization units listed in Annex 1.

Immunisation campaign

The immunization campaign against COVID-19 is launched throughout the country and is organized at regional level by the RHI in accordance with the above cited *Order No. RD- 01-726 of 23.12.2021* of the Minister of Health.

Following a decision of the European Commission, vaccination against COVID-19 in the Member States will start with limited quantities of vaccine delivered in the last days of December 2020, with the first quantities arriving in Bulgaria on 26 December 2020.

Table 6 presents the sequence of vaccine authorisations granted within the EU and the first vaccine deliveries in the country, as published on the European Medicines Agency (EMA) website and the COVID-19 Unified Information Portal.

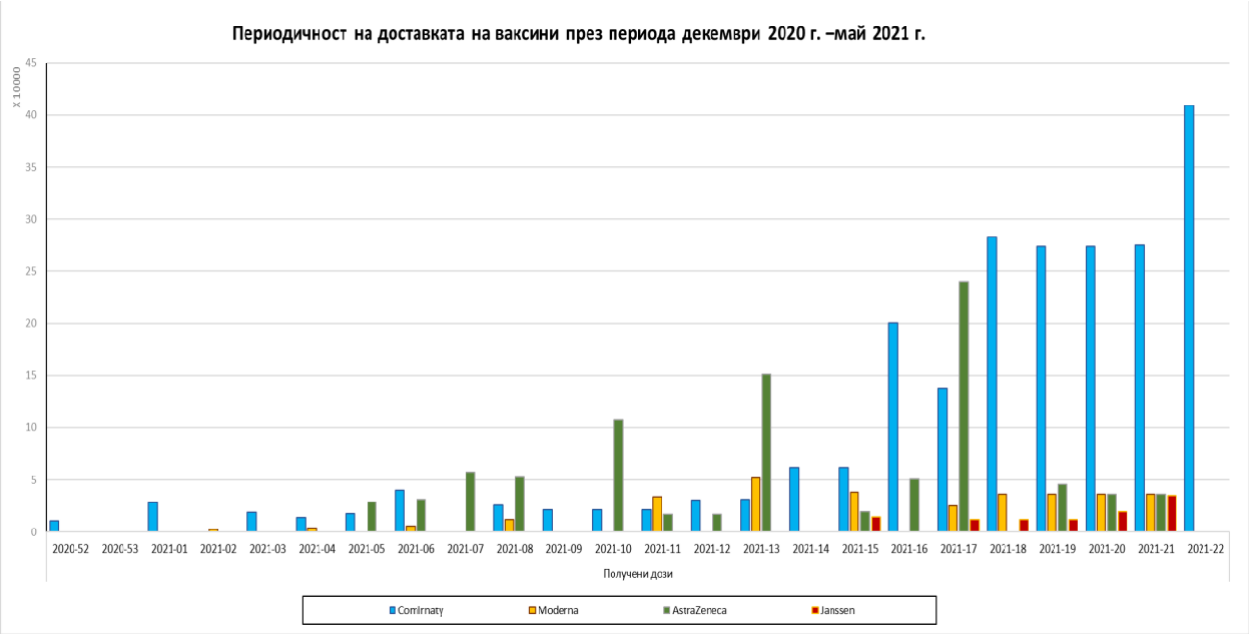
Table 6. Chronology of the first COVID-19 vaccine deliveries authorised in the EU

Vaccine - type	Authorised for use in the EU (date)	First delivery in Bulgaria (date)
PfizerBioNTech Comirnaty	21.12.2021	26.12.2020
Moderna	06.01.2021	13.01.2021
Astra Zeneka (now Vaxzevria)	29.01.2021	07.02.2021
Janssen	11.03.2021	15.04.2021

Sources: EMA, Unified Information Portal

Figure 84 shows the chronology of COVID-19 vaccine deliveries on a weekly basis for the period December 2020 to 31 May 2021. It can be seen that at the end of 2020 and the first weeks of 2021 (January) the supply of doses of the first authorised vaccine—PfizerBioNTech Comirnaty—is relatively limited in quantity. Thereafter, deliveries become more regular, with varying quantities, while gradually including the other three authorised vaccines.

Fig. 84



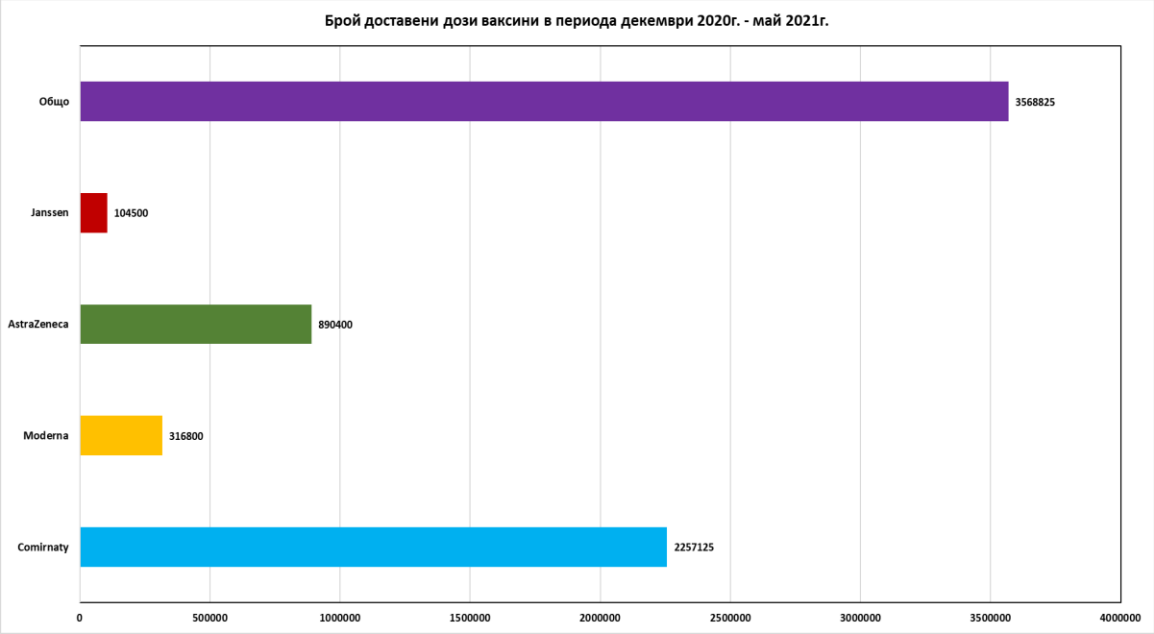
Sources: European Centre for Disease Prevention and Control (ECDC)[25]

A relatively more stable upward trend in supply is observed from the end of March and more noticeably in the second half of April 2021 (week 16), with the trend remaining steady until the end of the observation period.

According to data available on the European Centre for Disease Prevention and Control (ECDC) website, a total of 3,568,825 vaccine doses from the four manufacturers had been received in the country by the end of May 2021. The largest amount is from PfizerBioNTech Comirnaty (2,257,125 doses), followed by the other two two-dose vaccines, Astra Zeneka (890,400 doses) and Moderna (316,800 doses). Relatively smaller quantities were obtained from the single-dose Janssen vaccine (104,500 doses). (Figure 85)

[25] https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#distribution-tab

Fig. 85



Source: ECDC

Based on the information provided by the MoH, the vaccination campaign was implemented in the following sequence:

From 27.12.2020, the coverage of the target groups of Phase I of the Plan was launched. In January 2021, the quantities of vaccines delivered were increased gradually, covering the Phase I target groups, with an initial priority to medical staff in the COVID-19 wards of the hospital care facilities, and then to medical staff in pre-hospital care, including pharmacists and dentists.

From the beginning of February, due to a decrease and even exhaustion of persons willing to receive vaccination under Phase I, Phase II of the vaccination campaign also started. Subject to the number of people willing to be vaccinated, the number of vaccination units in the different districts and the availability of vaccines in the country, Phases I and II are proceeding in parallel in February.

Later in February, following a decision of the NVS, it is permitted, where possible, to simultaneously vaccinate persons in Phase II and Phase III of the NVP against COVID-19. Phase III was launched first in Sofia with a decision of the NVS on 08.02.2021 to start the coverage of willing persons from the Ministry of Interior and the Ministry of Defence with the Astra Zeneka vaccine, and vaccinations to be administered by their medical entities.

With regard to the forthcoming parliamentary elections on 4 April 2021, the Council of Ministers adopted Decision No. 91/03.02.2021, according to which Phase III of the NVP against COVID-19 includes the persons who will be directly involved in the organisation and conduct of the electoral process, as well as with the digital processing of voting data— the members of the Central Electoral Commission (CEC), of the district and sectional electoral commissions, the CEC administration staff, the experts and technical assistants assigned by the CEC and the Regional Electoral Commissions (REC) to the electoral process, the Ministry of Interior staff responsible for logistics and security of election papers and premises, the experts of 'Information Services' JSC, who at the level of the CEC and the REC will carry out the computer processing of the voting data and will prepare the issuance of the ballot paper with the results of the election, including machine voting; the experts of 'Siela Norma' JSC who will perform the activities and processes that constitute the logistical support and servicing of the specialized electronic voting machines.

Decision No. 144/19.02.2021 adds text to permit—on an exceptional basis and subject to availability of sufficient quantities of vaccines against COVID-19—vaccination on Saturdays and Sundays and of persons who do not fall within the target groups of Phase I to V, provided that they have expressed a wish to do so. With Decision No. 145/22.02.2021 of the Council of Ministers the administering of vaccinations is extended to the weekday afternoons.

On 15.02.2021 the Staff decided that, in view of the expected sufficient vaccine quantities during March, phases I-IV should be overlapped and that the preparation of the mass vaccination should be intensified by opening the vaccination units on weekends. From mid-February 2021, the increased vaccine quantities and the increased number of deliveries make it possible to also vaccinate persons aged 65 and over and those with concomitant chronic diseases, i.e., Phase IV persons. From the beginning of April 2021, the main priority is to supply GP's with half of all vaccine supplies of all types.

Phase V was launched effectively with a positive decision by the NVS on 05.04.2021 and a follow-up letter in response to an enquiry from the Ministry of Justice about the possibility of vaccinating prisoners in detention facilities.

On 21.04.2021, on the website of the Ministry of Health as well as in the Unified Information Portal, the decisions of the NVS on the behaviour of persons who have received the first dose of Astra Zeneka vaccine and the administration of the vaccine in women under 60 years of age related to an increased risk of thromboses and/or a history of thrombocytopenia were published. As a result of the increased quantities of vaccine being supplied in the country since the end of April, vaccination has been extended to all persons in the country.

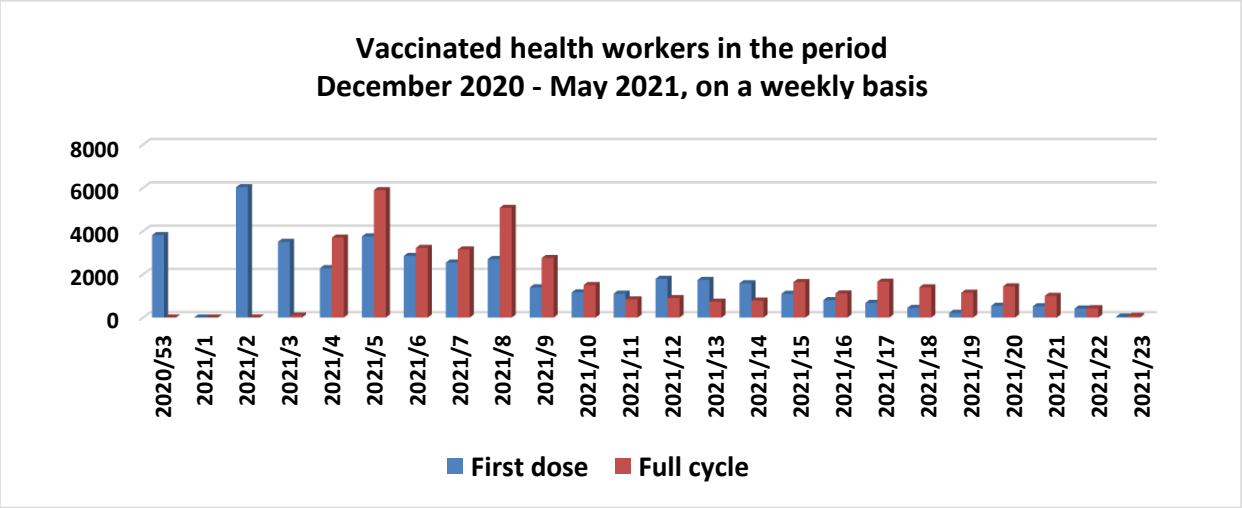
Vaccinations by 31.05.2021 in the country according to the above-mentioned phases/priority groups

Vaccinated medical personnel

The group includes doctors, dentists, support staff to Phase I, e.g., in medical facilities, health care specialists (according to MoH data). In the period December 2020-May 2021, 41,031 health workers were vaccinated with a first dose and 38,551 health workers were vaccinated with the full vaccination cycle.

Figure 86 presents the number of vaccinated health workers in the country on a weekly basis for the same period. The number vaccinated in December 2020 and January-February 2021 is significantly higher compared to the period March-April-May 2021.

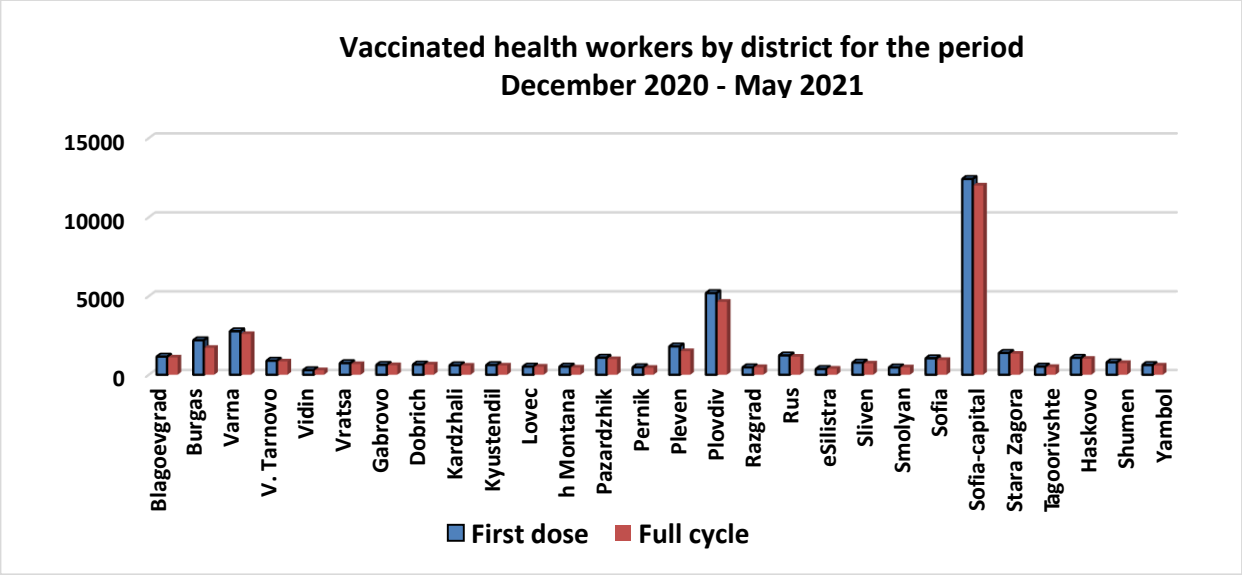
Fig. 86



Source: MoH

By district, the highest number of vaccinated health workers was in Sofia-city, followed by Plovdiv and Varna. Due to the lack of data on the number of health workers per district, it is not possible to calculate the relative share of vaccinated. (Figure 87)

Fig.87

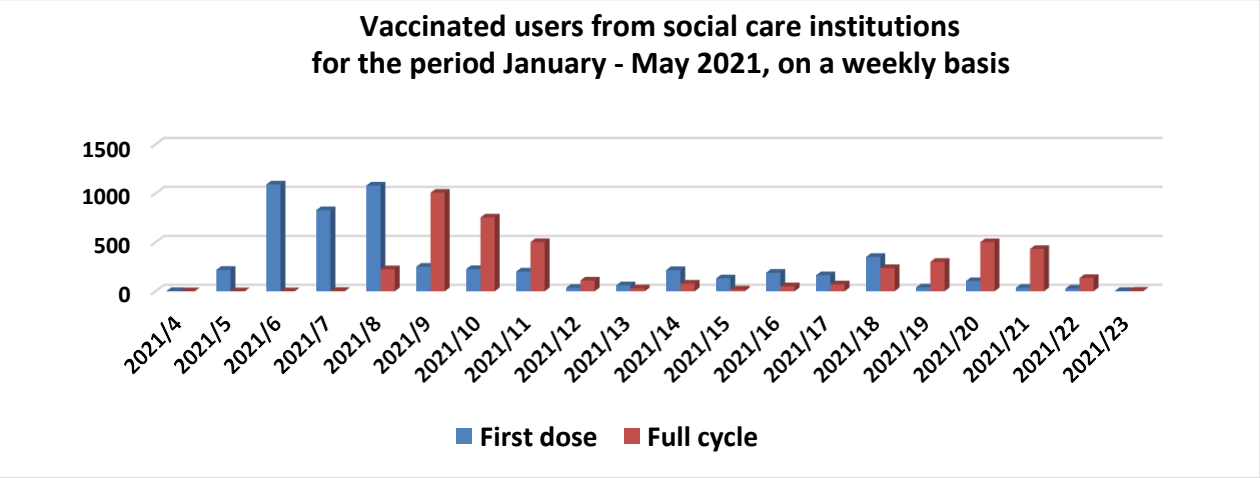


Source: MoH

Vaccinated users from social service institutions[26]

Between January and May 2021, 5,248 users from social service institutions were vaccinated with the first dose and 4,454 completed the full vaccination cycle. When tracked on a weekly basis, a higher proportion of vaccinated persons can be seen at the start of the campaign in February and the first weeks of March, with some increase in coverage also seen in May. (Figure 88)

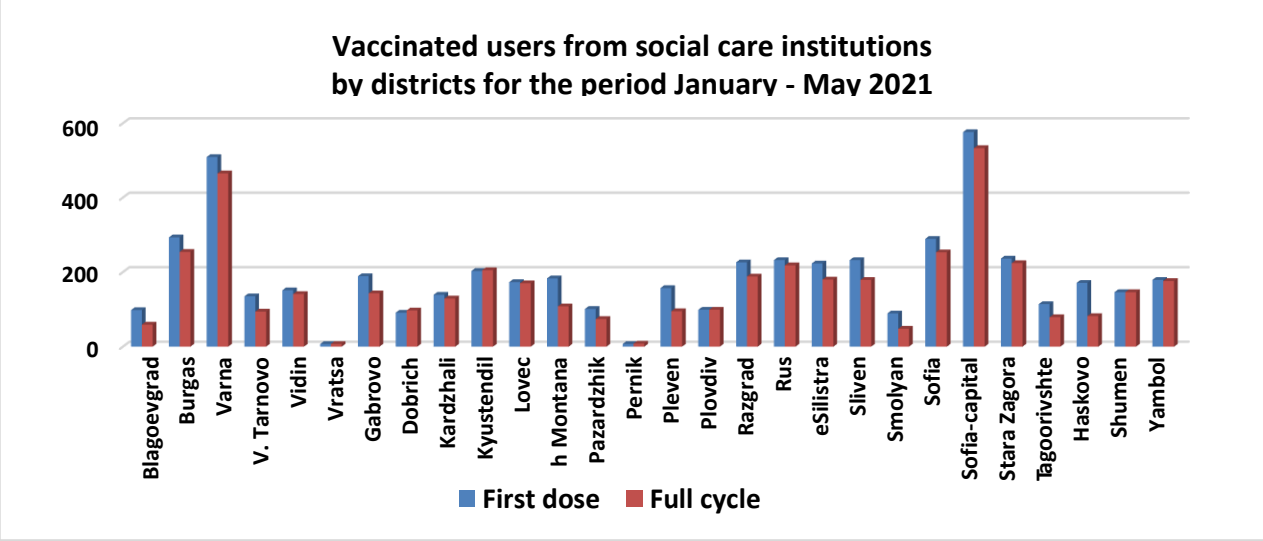
Fig. 88



Source: MoH

By district, the highest proportion of vaccinated users from social service institutions was in Sofia-city, followed by Varna and Burgas. Data on the number of users from social service institutions are not available, so it is not possible to determine the relative share. (Figure 89)

Fig. 89

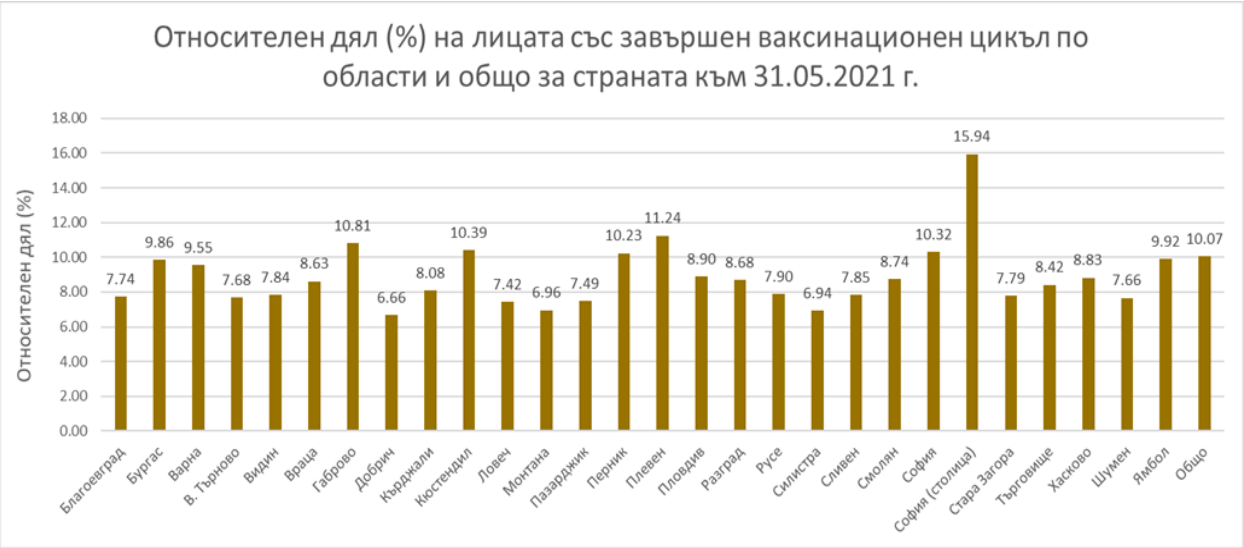


Source: MoH

[26] Including for residential care.

Vaccination coverage (completed cycle) in the country and by district by the end of May 2021
The national average vaccination completion rate at the end of May 2021 is 10.07%. The highest relative coverage is in the districts of Sofia-city (15.94%) and Pleven (11.24%), followed by Gabrovo (10.84%) and Kyustendil (10.39%). Sofia (10.32%) and Pernik (10.23%) are also slightly above the national average. Comparatively, the lowest values are in the districts of Dobrich (6.66%), Silistra (6.94%) and Montana (6.96%).[27] (Figure 90)

Fig. 90



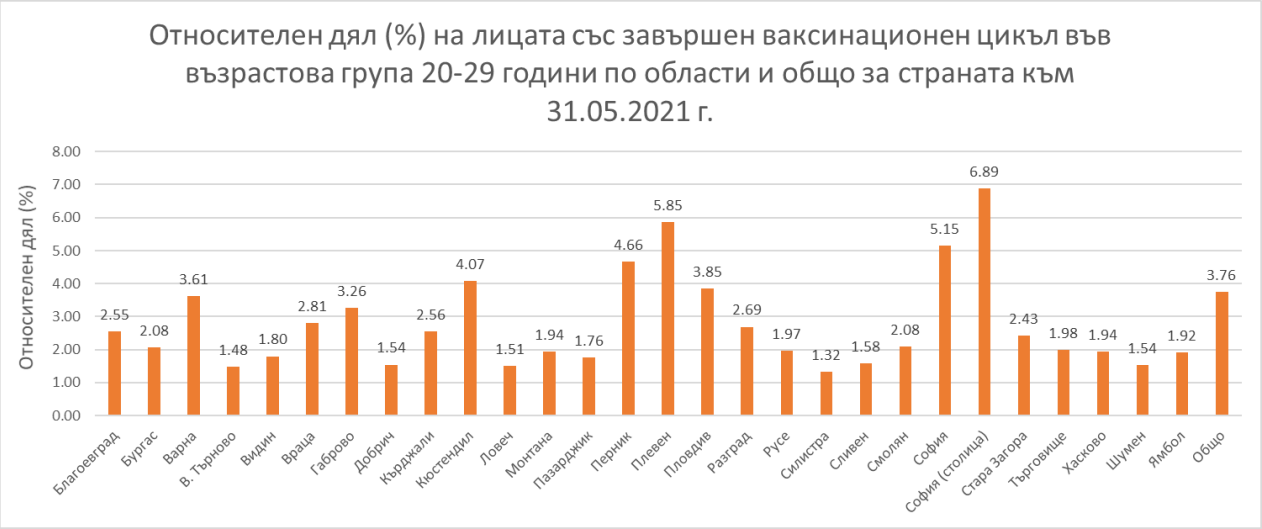
Sources: MoH, NSI

The following figures present the relative proportion of persons with a completed vaccination cycle against COVID-19 at the end of May 2021 in the country and by district, in the respective age groups 20-29, 30-39; 40-49; 50-59; 60-69; 70-79; 80-89 and 90+ years. The 0-19 age group is not considered given that it is not among the priority groups for vaccination. The data show that 0.51% of all individuals with a completed vaccination cycle in the country fall into the latter group.

The data show that for the observed period, the average proportion of persons with completed vaccination against COVID-19 in the age group 20-29 years in the country was 3.76%. The highest coverage was in Sofia-city district (6.89%), followed by Pleven (5.85%) and Sofia (5.15%). Pernik and Kyustendil are in the range of 4.66-4.07%. The share of persons with a completed immunization schedule is also around the national average in the districts of Plovdiv and Varna (3.85% and 3.61%, respectively). Comparatively, the lowest coverage rates in this age group were observed in the districts of Silistra (1.32%), V. Tarnovo (1.48%) and Lovech (1.51%). (Figure 91)

[27] The data on the number of persons with completed vaccination coverage in the respective district (on a weekly basis for 2020 and 2021) are provided by the MoH, and those for the population (as of 31.12.2020) by district and age are provided by the NSI.

Fig.91



Sources: MoH, NSI

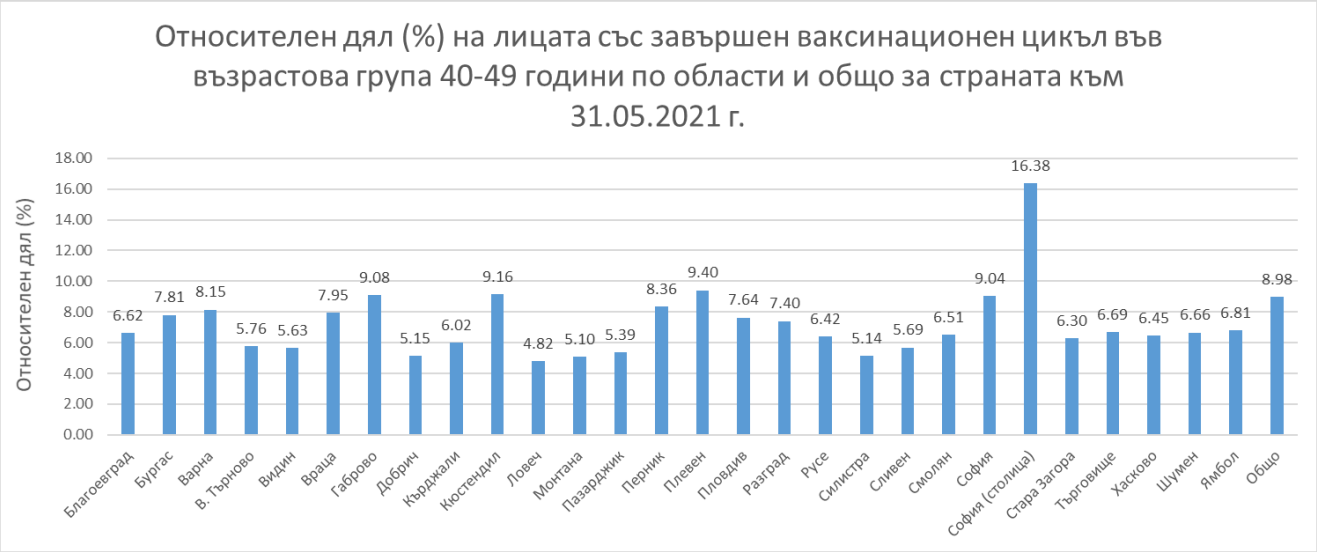
In the age group 30-39 years, the proportion of immunized with completed cycle in the country was 6.17%. The highest relative coverage was observed in Sofia-city (11.48%), followed by Sofia-region (8.43%), Pernik (8.15%) and Pleven (6.42%). The lowest share is in the districts of Lovech (2.80%), V. Tarnovo (2.83%), Dobrich (2.94%). (Figure 92)

Fig.92

Sources: MoH, NSI

In the 40-49 age group, the overall proportion of vaccine completion in the country increased to 8.98%. There is also a significantly higher coverage in the district of Sofia-city (16.38%). The relative proportion was above the national average in the districts of Pleven (9.40%), Kyustendil (9.16%), Gabrovo (9.08%) and Sofia-region (9.04%). A number of districts, including Lovech (lowest range of 4.82%), Montana (5.10%), Silistra (5.14%), Dobrich (5.15%), and Pazardzhik (5.39%), are in the range of 5%. (Figure 93)

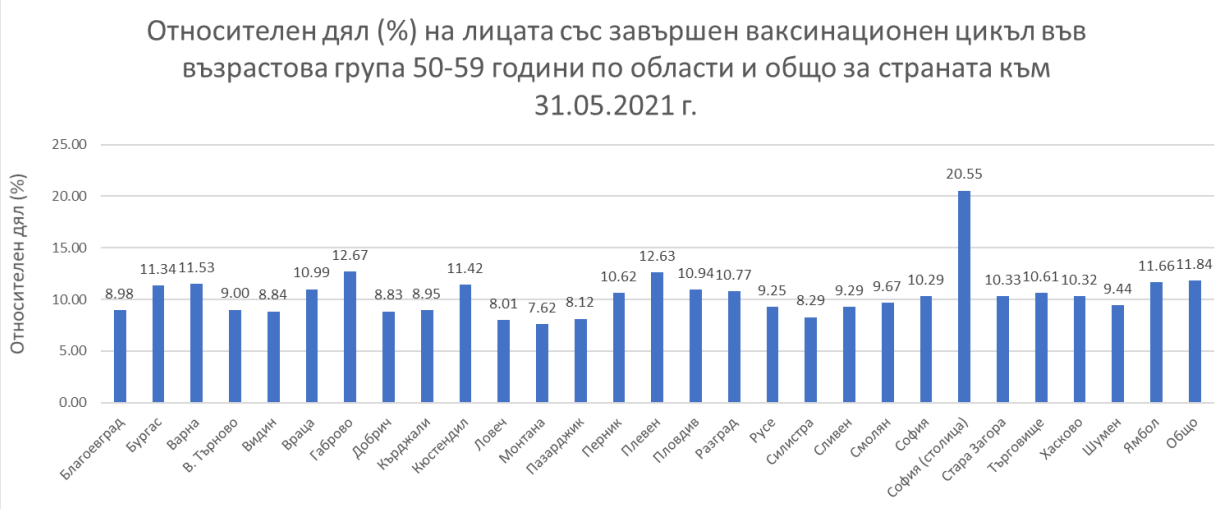
Fig. 93



Sources: MoH, NSI

The average vaccination coverage in the 50-59 age group was 11.84%, compared to a significantly higher coverage in Sofia-city (20.55%). The districts of Gabrovo (12.67%) and Pleven (12.63%) are also above the national level. In the remaining districts the relative coverage fluctuates, being the lowest in Montana (7.62%), Lovech (8.01%), Pazardzhik (8.12%), and Silistra (8.29%). (Figure 94)

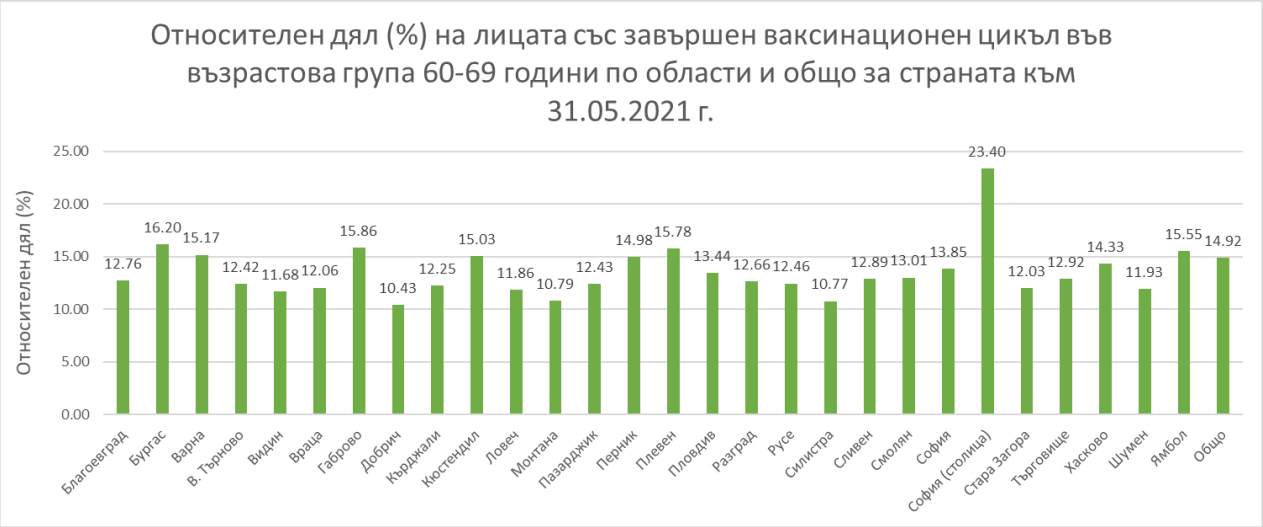
Fig. 94



Sources: MoH, NSI

With an average proportion of 14.92% of persons with completed vaccination cycle in the 60-69 years group, it is again the highest in Sofia-city (23.40%). The coverage is also above the national average in the districts of Burgas (16.20%), Gabrovo (15.86%), Pleven (15.78%), Yambol (15.55%), Pernik (14.98%). The lowest share is in the districts of Dobrich (10.43%), Silistra (10.77%), Montana (10.79%). (Figure 95)

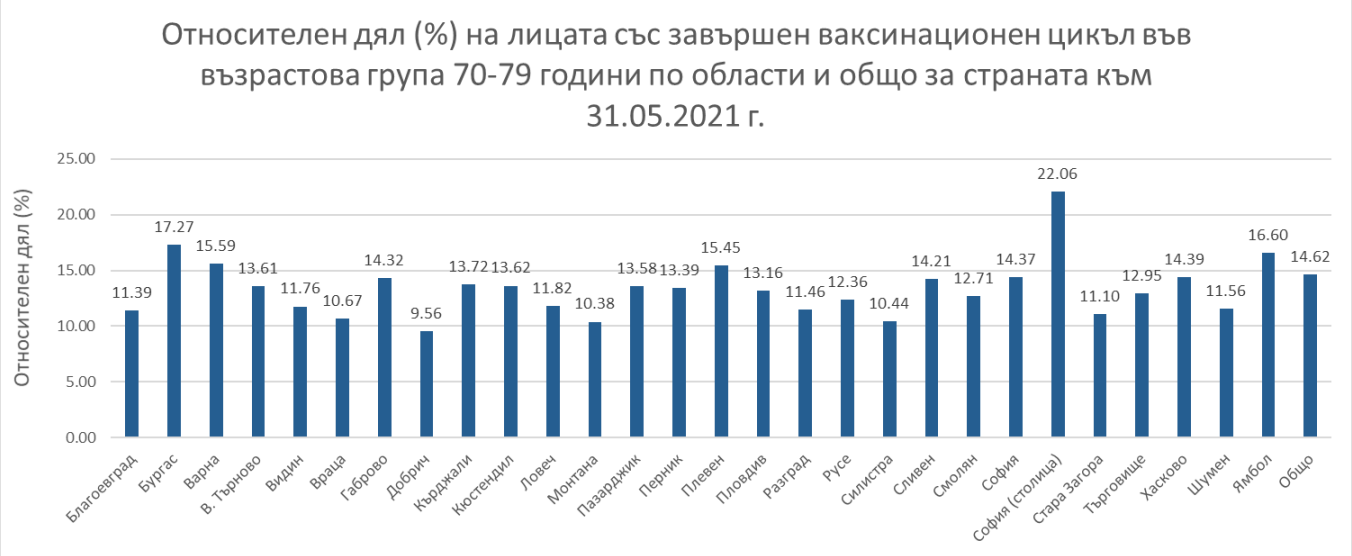
Fig. 95



Sources: MoH, NSI

With an average national share of 14.62%, the highest share in the 70-79 age group was again in Sofia-city (22.06%), followed by Burgas (17.27%) and Yambol (16.60%). The districts of Varna (15.59%) and Pleven (15.45%) are above the national average and slightly above 15%. The lowest relative coverage is in the districts of Dobrich (9.56%), Montana (10.38%), Silistra (10.44%) and Vratsa (10.67%). (Figure 96)

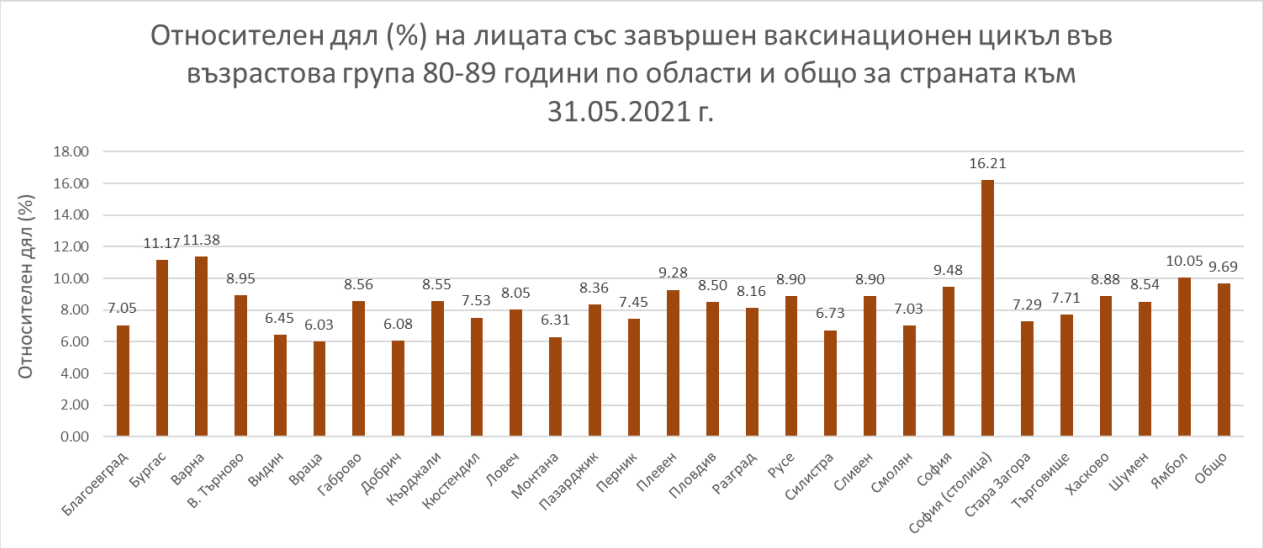
Fig. 96



Sources: MoH, NSI

With an average national share of 14.62%, the highest share in the 70-79 age group was again in Sofia-city (22.06%), followed by Burgas (17.27%) and Yambol (16.60%). The districts of Varna (15.59%) and Pleven (15.45%) are above the national average and slightly above 15%. The lowest relative coverage is in the districts of Dobrich (9.56%), Montana (10.38%), Silistra (10.44%) and Vratsa (10.67%). (Figure 96)

Fig. 97



Sources: MoH, NSI

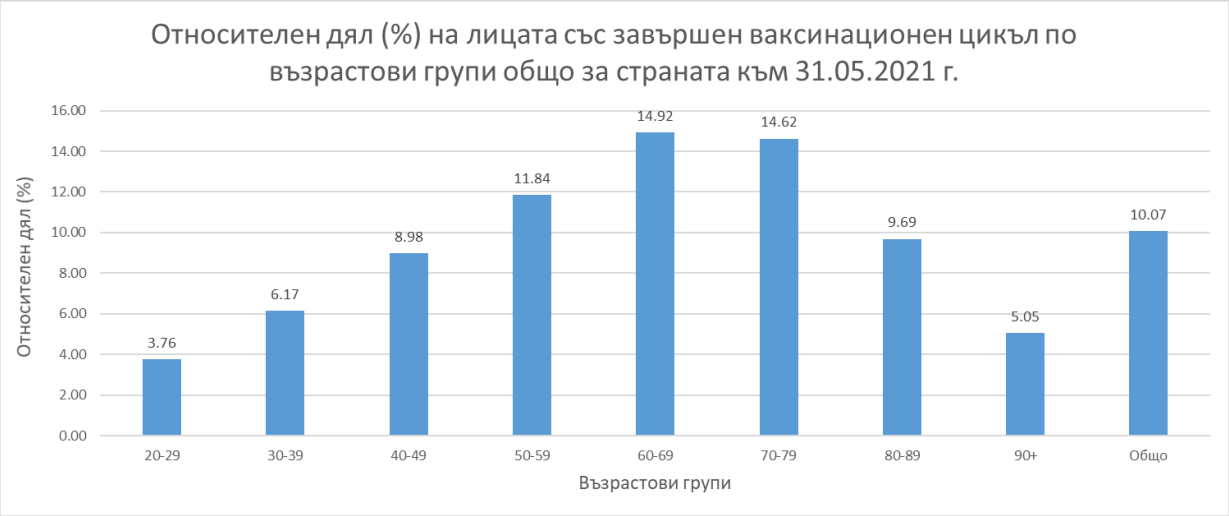
The national average relative share for the 90+ age group is 5.05%. The maximum value is in Sofia-city (8.18%), followed by the districts of Yambol (6.46%), Sofia-region (6.10%) and Gabrovo (5.99%). The lowest relative share is in the districts of Targovishte (2.05%), Silistra (2.15%), Montana (2.45%), Vratsa (2.61%). (Figure 98)

Fig. 98

Sources: MoH, NSI

As of 31.05.2021, with an average full vaccination coverage of 10.07% of the adult population (20+ to 90+), the highest proportion of at-risk age groups is 60-69 years (14.92%) and 70-79 years (14.62%), followed by the 50-59 group (11.84%). Comparatively, there is a descending order of covered persons in the more active ages – 40-49, 30-39 and 20-29. Correspondingly, the coverage is lower in the 80-89 age group and lowest in the oldest age group (90+). (Figure 99)

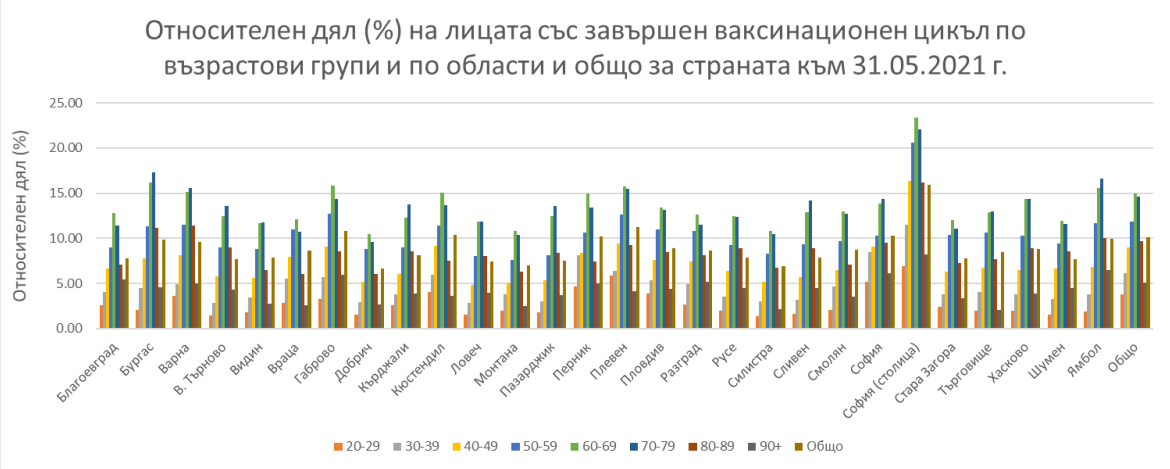
Fig. 99



Sources: MoH, NSI

Data on the relative proportion (%) of vaccine completers by age group, district and country are summarised in Figure 100.

Fig. 100



Sources: MoH, NSI

Findings

1. At the national level, an organization for the vaccination process has been established through the adoption of a National Vaccination Plan against COVID-19 and the formation of a National Vaccination Task Force to coordinate and control its implementation.
2. Priority vaccination phases and at-risk groups are defined and adapted to the specific needs and setting when implementing the vaccination process.
3. The provision of vaccines in Bulgaria has started immediately after receiving permission from the relevant European structures.
4. The supply of vaccines continues on a regular basis, with a gradual inclusion of all vaccines authorised in the EU and a continuous increase in their quantities.
5. The distribution of vaccines is determined centrally, whilst the immunization campaign against COVID-19 is organized at the regional level by the RHI.
6. The vaccination process starts with coverage of the target groups of Phase I of the Plan, with initial priority given to frontline medical staff, and continues in phases for the target groups of Phases I-V, with the possibility of vaccination of non-target groups, if there is a willingness and availability of vaccines.
7. By the end of May 2021, the relative proportion of people with completed vaccination is low (10.07% national average), with the highest vaccination coverage nationally in the 60-69 (14.92%) and 70-79 age groups (14.62%), and a mere 3.76% in the 20-29 age group.

A large volume of data on COVID-19 vaccines, the vaccination process and vaccination coverage in the country has been accumulated and is regularly reported to EU and WHO specialised bodies, however without being summarised in an appropriate format and published periodically on the Unified Information Portal.

Conclusion

The coronavirus pandemic was unexpected and put all health and social systems in countries around the world to the test. Bulgaria was not an exception to this rule, moreover, it turned out that it entered into the pandemic with a number of public health problems. The crisis revealed all the ills and shortcomings of the health system, which had been systematically neglected and underestimated over the last two decades. It has brought to the fore the question of the health of the Bulgarian population and its chances for survival in the new century. The unexpectedly high extraordinary mortality rates at the two pandemic peaks in 2020 and 2021 have internationally placed Bulgaria at the top of the global negative charts. The underlying causes of this excess mortality in all cases are complex and multifactorial, i.e., there is no unique factor that can explain what has happened in the past ten months. Thus, the analysis of what has happened requires a careful assessment of all the causes that have led to this unfortunate outcome. The causes therefore can be grouped into the following categories.

1. The state of the public health and the health-demographic indicators of the Bulgarian people, with which they are facing the pandemic.
2. The state of the health system in all its aspects:
   - the primary outpatient care;
   - the specialized outpatient care;
   - the hospital care;
   - the emergency medical care;
   - the human resources;
   - the information provision;
   - the financial provision;
   - the pharmaceutical sector.
3. The organization and response to the pandemic as reflected in:
   - lack of a communication strategy;
   - lack of a systematic risk assessment;
   - lack of a strategic plan to deal with an epidemic threat;
   - lack of unity on the medical aspects of the pandemic;
   - lack of standards and protocols for the treatment of the coronavirus infection;
   - lack of adequate and sufficient funding from the beginning of the pandemic.

Each of the issues described above will be addressed separately.

Poor state of the public health and poor health-demographic indicators of the Bulgarian population

Bulgaria's health and demographic indicators have consistently been below the EU average in recent decades. They are not only of crucial importance for the well-being of citizens, but also constitute an important factor in driving economic growth. Their current state is a reflection of a number of factors in recent years—significant shifts in the age structure of the population, influenced by changes in fertility, mortality, life expectancy, migration, living standards, political changes, etc. At the same time, it should be noted that trends in health and demographic indicators do not correspond to the financial injections into the system. The reasons for this are twofold: an insufficient efficiency of medical care (despite the high quality of medical services) and insufficient financing of preventive and health-promoting programmes.

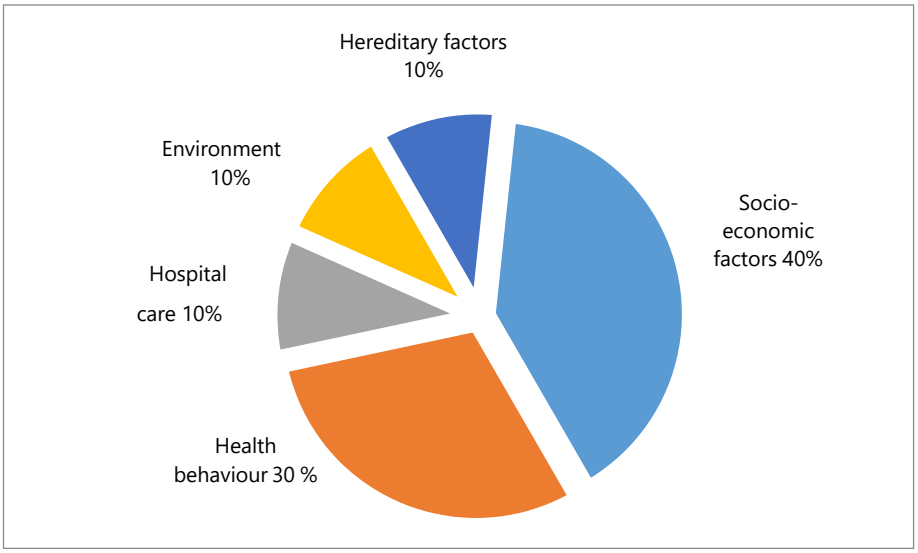
There has been a steady upward trend in spending on treatment and medicines—both public and private. Expenditures on hospital care, diagnostics and costly treatments are rising. On the other hand, public health spending is dramatically disproportionate to that on medical activities.

Public health investments, such as preventive care and health promotion, are known to pay for themselves many-fold through savings on medicines and expensive medical treatments. The value of the public health approach in the health care system is that with relatively little investment on a population level, an enormous long-term effect is achieved that ultimately leads to the aforementioned savings in the curative field.

According to conducted studies and analyses, it has been evidenced that the main determinants of health have different levels of impact and contribution to the health status of the population at the population level. Figure 101 shows that socio-economic factors have a leading contribution to the overall population health. Health determinants related to health behaviour and the environment are also prominent, accounting for a total contribution of 40%.

Here is the relevance and importance of the public health system and activities towards its improvement.

Fig. 101 Determinants of health

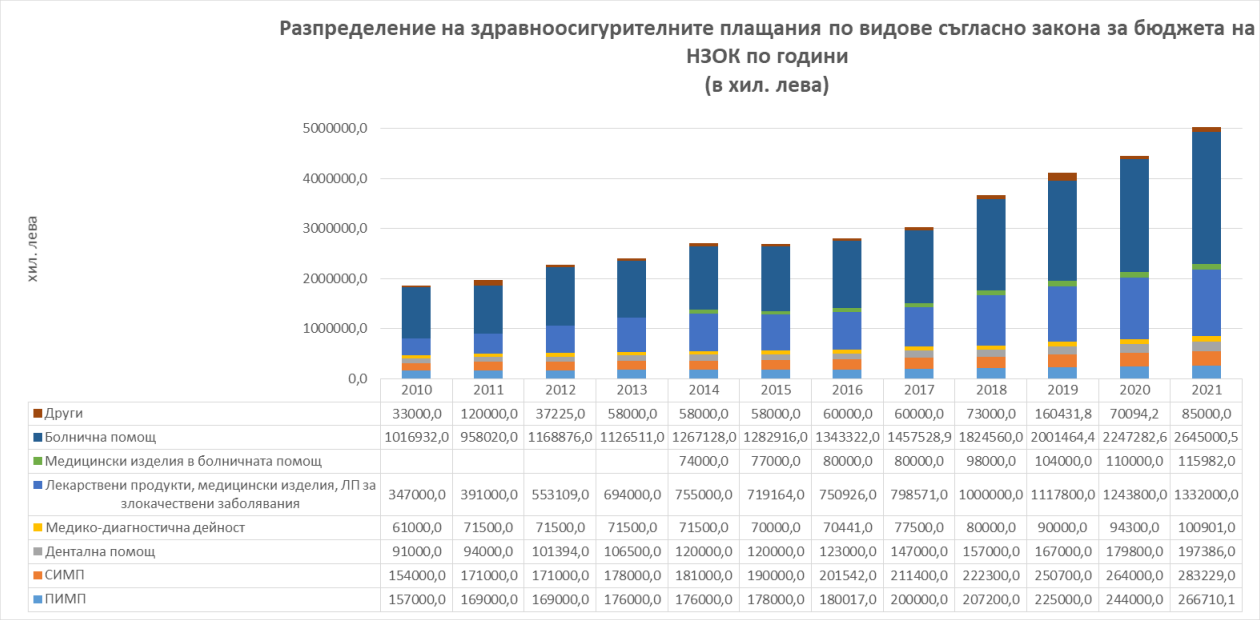


Sources: Tarlov AR. Ann N Y Acad Sci 1999; 896: 281-93; and Kindig D, Asada Y, Booske B. JAMA 2008; 299(17): 2081-2083.

Investing into the public health is an investment in the future with a long-term perspective for the health and well-being of the Bulgarian population. But in reality, the state of financing in activities aimed at strengthening and protecting public health does not support the above statement, which has been known for many years and which has been presented in numerous professional and scientific forums, including at the highest government level.

An indicator of a given government's policy is the distribution of public finances across different sectors. For the period 2010-2021 (Figure 102), an increase is observed in all health insurance payments in accordance with the laws adopted for each year for the NHIF budget for the respective year, mainly at the expense of funds for pharmaceutical products (including those for malignant diseases and medical devices), which is over 380%, and for hospital care, which is 260%. At the same time, the rate of growth of expenditure on primary outpatient care and specialised outpatient care is significantly lower, with an increase of 169% for primary outpatient care and 184% for the specialists of outpatient medical care.

Fig. 102

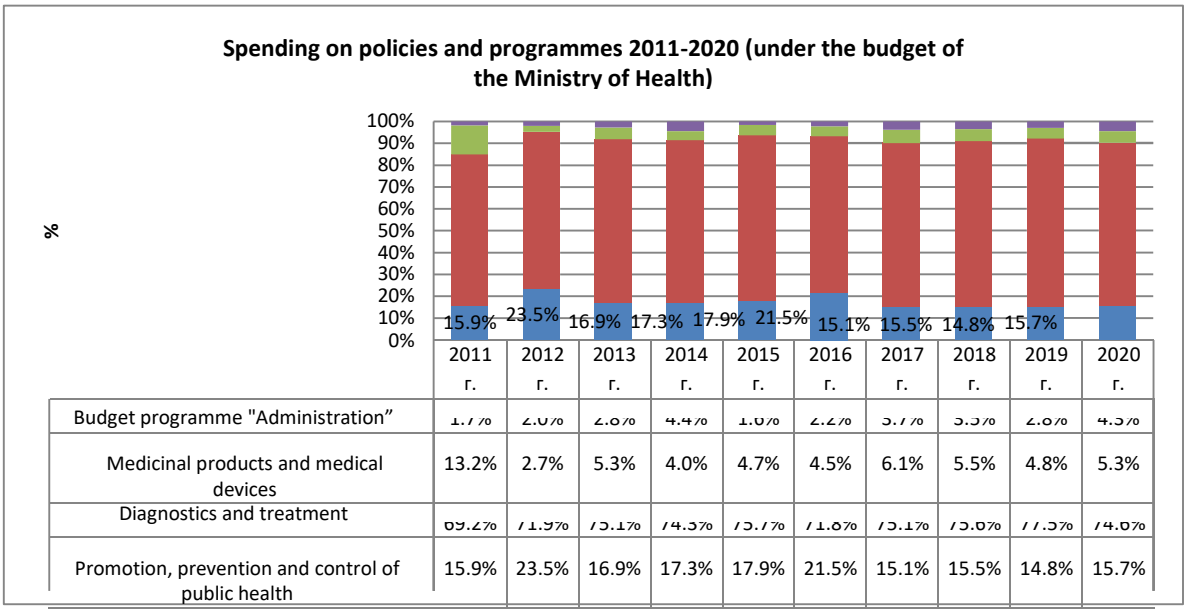


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Други	33000,0	120000,0	37225,0	58000,0	58000,0	58000,0	60000,0	60000,0	73000,0	160431,8	70094,2	85000,0
Болнична помощ	1016932,0	958020,0	1168876,0	1126511,0	1267128,0	1282916,0	1343322,0	1457528,9	1824560,0	2001464,4	2247282,6	2645000,5
Медицински изделия в болничната помощ					74000,0	77000,0	80000,0	80000,0	98000,0	104000,0	110000,0	115982,0
Лекарствени продукти, медицински изделия, ЛП за злокачествени заболявания	347000,0	391000,0	553109,0	694000,0	755000,0	719164,0	750926,0	798571,0	1000000,0	1117800,0	1243800,0	1332000,0
Медико-диагностична дейност	61000,0	71500,0	71500,0	71500,0	71500,0	70000,0	70441,0	77500,0	80000,0	90000,0	94300,0	100901,0
Дентална помощ	91000,0	94000,0	101394,0	106500,0	120000,0	120000,0	123000,0	147000,0	157000,0	167000,0	179800,0	197386,0
СИМП	154000,0	171000,0	171000,0	178000,0	181000,0	190000,0	201542,0	211400,0	222300,0	250700,0	264000,0	283229,0
ПИМП	157000,0	169000,0	169000,0	176000,0	176000,0	178000,0	180017,0	200000,0	207200,0	225000,0	244000,0	266710,1

Source: NHIF

The analysis of the spending on policies and programs of the budget of the Ministry of Health by individual policies shows that the spending on the policy "Promotion, prevention and control of the public health" in recent years amounts to about 15% of the total spending on policies of the MoH, which is extremely insufficient and demonstrates that they are not of high priority. Their share was highest in 2016, after which it decreased and has remained stable at around 15%. (Figure 103)

Fig. 103

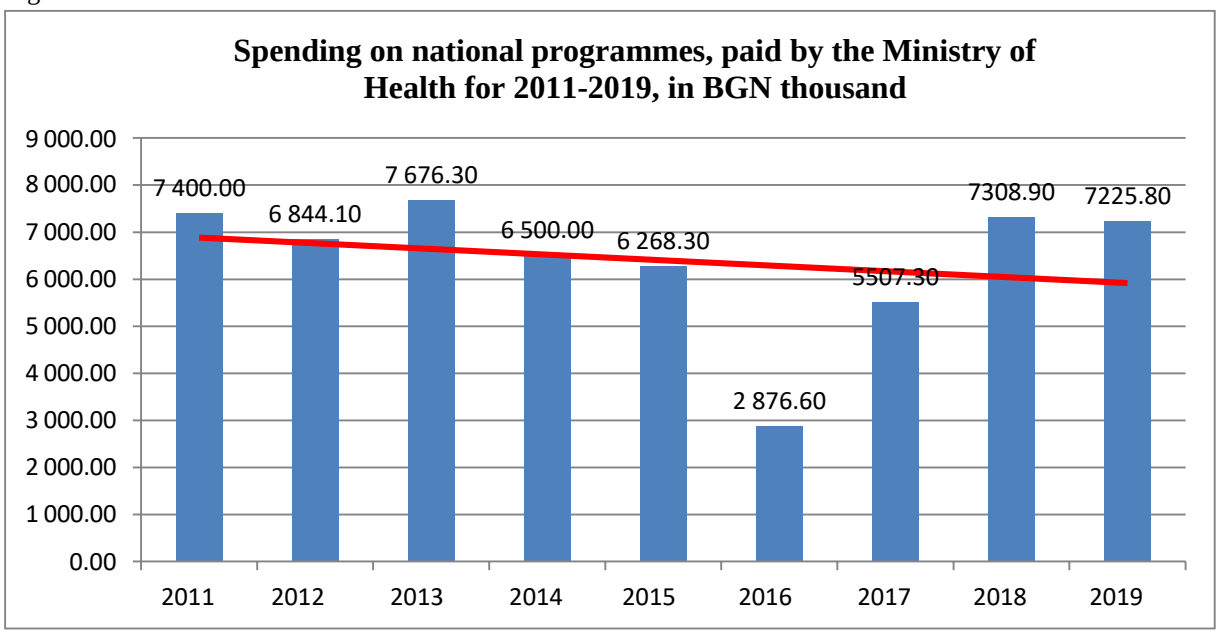


	2011 г.	2012 г.	2013 г.	2014 г.	2015 г.	2016 г.	2017 г.	2018 г.	2019 г.	2020 г.
Budget programme "Administration"	1.7%	2.0%	2.6%	4.4%	1.6%	2.2%	3.7%	3.3%	2.6%	4.3%
Medicinal products and medical devices	13.2%	2.7%	5.3%	4.0%	4.7%	4.5%	6.1%	5.5%	4.8%	5.3%
Diagnostics and treatment	69.2%	71.9%	75.1%	74.3%	75.7%	71.8%	75.1%	75.6%	77.3%	74.6%
Promotion, prevention and control of public health	15.9%	23.5%	16.9%	17.3%	17.9%	21.5%	15.1%	15.5%	14.8%	15.7%

Source: NHIF

Included in this programme are the budget programme "State Health Control", the budget programme "Promotion and Prevention of Non-Communicable Diseases", the budget programme "Prevention and Surveillance of Communicable Diseases", the budget programme " Reducing the Demand for Narcotic Substances" and, until 2011, the programme "Secondary Disease Prevention". One of the key elements in the implementation of public health policy is the establishment and implementation of national programmes, which are financed from the MoH budget and respectively the state budget. (Figure 104)

Fig. 104

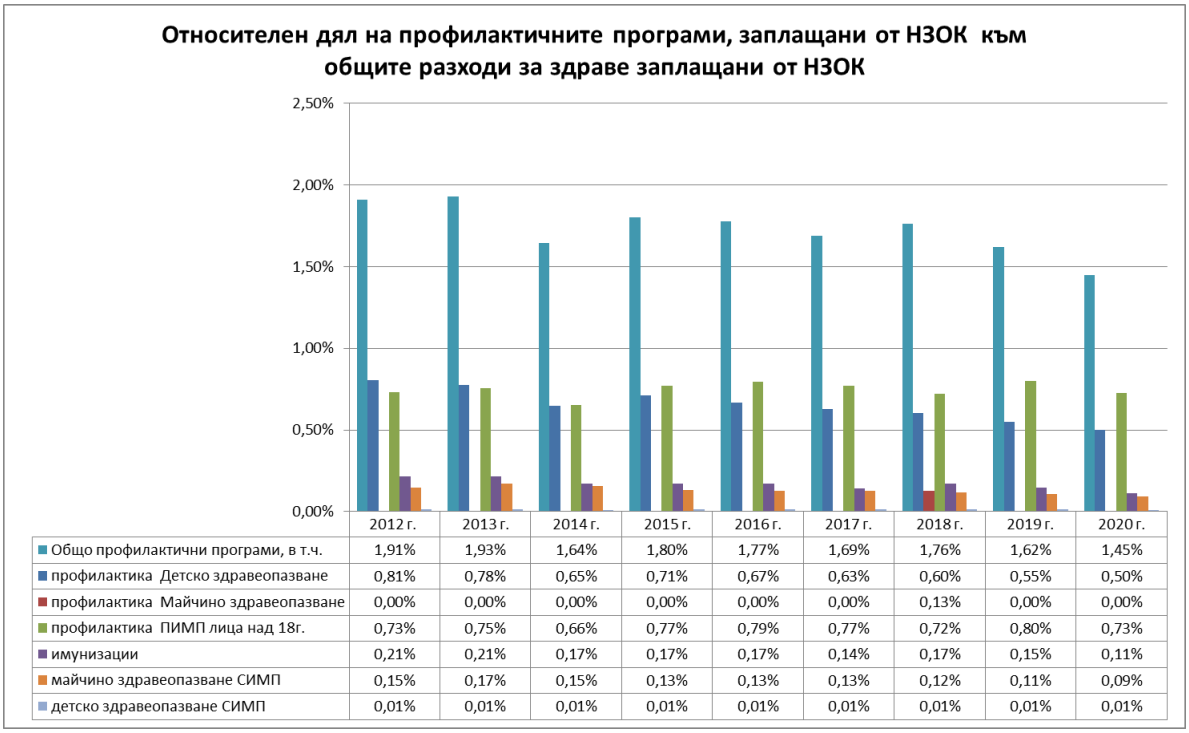


Source: NHIF

It is evident that the funds ahead of 2019 are comparable to those of 2011, and they have been continuously decreasing until 2017. It is precisely through funding national programmes in the field of public health that a significant effect can be achieved at the population level to improve the health of the population through health promotion and prevention of communicable and non-communicable diseases, thereby reducing the number of persons requiring medical care in health facilities, which in turn leads to a reduction in costs in the health system. This is an alphabetical truth that has been known for many years, which is often repeated and put forward as a necessary action, but which, unfortunately, has hitherto always remained in the realm of good intentions.

The data on spending on prevention through NHIF's prevention programmes also show that the funds allocated to prevention in relation to the overall NHIF spending are extremely low at less than 2% per year, with a downward trend after 2012—moving from 1.91% to 1.45% in 2020. (Figure 105)

Fig. 105



	2012 г.	2013 г.	2014 г.	2015 г.	2016 г.	2017 г.	2018 г.	2019 г.	2020 г.
Общо профилактични програми, в т.ч.	1,91%	1,93%	1,64%	1,80%	1,77%	1,69%	1,76%	1,62%	1,45%
профилактика Детско здравеопазване	0,81%	0,78%	0,65%	0,71%	0,67%	0,63%	0,60%	0,55%	0,50%
профилактика Майчино здравеопазване	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,13%	0,00%	0,00%
профилактика ПИМП лица над 18г.	0,73%	0,75%	0,66%	0,77%	0,79%	0,77%	0,72%	0,80%	0,73%
имунизации	0,21%	0,21%	0,17%	0,17%	0,17%	0,14%	0,17%	0,15%	0,11%
майчино здравеопазване СИМП	0,15%	0,17%	0,15%	0,13%	0,13%	0,13%	0,12%	0,11%	0,09%
детско здравеопазване СИМП	0,01%	0,01%	0,01%	0,01%	0,01%	0,01%	0,01%	0,01%	0,01%

Source: NHIF

The above data are evidence that health promotion and prevention activities are underfunded, which in turn leads to a deterioration in the health status of the population, especially with regard to chronic non-communicable diseases (cardiovascular diseases, oncological diseases, diabetes and chronic respiratory diseases), which are the main cause of the high mortality in Bulgaria—both general and premature. Over 80% of deaths in Bulgaria are attributable to them, which requires decisive action to improve the health of the population in all age groups, to reduce mortality and extend life expectancy. It is exactly because of the awareness at state level of its importance and because of sustained sufficient funding and national actions through the involvement of all sectors of society that the countries of Western Europe have significantly better health and demographic indicators compared to Bulgaria. This also holds true for all other countries where health promotion and disease prevention are a sustainable public policy.

Priority should be given to the preventive and health-promoting programmes and human resource policies in the public health system. There is an extreme problem in terms of human resources in public health. In recent years, staffing levels in the RHI's and national public health centres have been repeatedly optimised (reduced), including through mergers of national centres, which has not led to improvements in performance. Trends linked to the reduction of budget programmes and the fund 'Working Salary' have led to a continuous reduction in the number of public health staff. The extremely low level of public health pay compared to all other structures in the health system and other sectors is leading to a massive exodus of highly qualified staff.

It is necessary to integrate public health principles and activities throughout all segments of society by engaging non-health sectors—health in all policies. Progress in terms of health and demographic indicators, the prevalence of risk factors, morbidity and mortality from major diseases can only occur after sustained action and effort over many years. The delayed impact of these actions is a reason for public health not being a sufficient focus of the health policies.

The most urgent key directions for development in this domain, on which measures can be proposed that would lead to a significant improvement in the overall state of the public health system, respectively to an improvement in the health and demographic indicators of Bulgaria, are:

Conducting in-depth analyses of morbidity and mortality, of the main determinants of health and social inequalities

The analyses will provide an evidence-based picture of the current state of the problem in the country, which will form the basis for health policy decisions. The data on morbidity and mortality will be collected on a regular basis in accordance with the National Statistical Programme approved annually by the Council of Ministers. The data on determinants and risk factors for health are not included in this type of analysis and will be collected through epidemiological surveys. These are conducted at population level in the country, but remain insufficient. There is a need to develop a system for continuous monitoring of these indicators by applying internationally validated methodology and design.

Establishing population-based registries of the most prominent diseases that contribute the most to high mortality in Bulgaria

There is a pressing need for registries on oncological diseases and diabetes. Regarding the cancer registry, there is one in Bulgaria (at the University Multi-profile Hospital for Oncology), but it needs to be improved so that it can provide real-time data and contain information to meet the needs of the health system management. A diabetes registry has been established at the NCPHA, but its operationalisation is linked to amendments in legal acts that have not been carried out so far.

Selecting effective interventions and programs to improve health under the existing budget constraints. Increasing the financing and improving the management of national programmes in public health

Bulgaria currently has existing national programmes in the field of public health. However, with regard to chronic non-communicable diseases, the only functioning programme is the National Programme for the Prevention of Non-Communicable Diseases. The prevention and control of chronic NCD's can lead to better health throughout the entire lifespan. According to the WHO, up to 80% of heart conditions, strokes, type 2 diabetes, and over one-third of cancers can be prevented by eliminating common risk factors—tobacco use, harmful alcohol use, unhealthy diet, and a lack of physical activity. The main interventions are both population-based, aimed at controlling behavioural risk factors (tobacco, alcohol, unhealthy diet, and physical inactivity), as well on individual-level services (targeting cardiovascular diseases, diabetes, and malignant neoplasms) that are closely linked to improving outcomes of chronic NCD's. The key interventions are cost-effective, evidence-based, have high impact, and are accessible and feasible across various health systems.

Obviously, this programme alone is not sufficient. It is mainly aimed at reducing the main risk factors and at early diagnosis. Separate programmes are needed for the main diseases, such as oncological diseases and diabetes. It is also particularly urgent to prepare and adopt a national programme and plan to combat cancer. The National Plan to Combat Cancer aims at reducing the number of cancer cases and related deaths and improving the quality of life of cancer patients through systematic and equitable implementation of evidence-based strategies for prevention, early

detection, diagnosis, treatment, rehabilitation, palliative care and research to identify innovative solutions and to evaluate the outcomes.

Developing and implementing long-term population screening programmes for the most significant diseases, especially oncological diseases

The purpose of screening is to identify individuals at higher risk of a disease or pathological condition in an apparently healthy population in order to offer earlier treatment or intervention, which in turn will improve the health status of some people who have undergone the screening. Screening programmes target large populations. This requires significant investments in equipment, personnel and information technologies, which can increase the burden on the health system.

There exist screening programs for various diseases. With regard to screening for malignant neoplasms, the Council of the European Union recommends the implementation of a systematic, population-based approach with quality assurance at all levels. The WHO and the EU recommend screening for breast, cervical and colorectal cancer. They account for 28% of cancer cases in the European region of the WHO. In the case of cervical cancer, screening allows cure at a precancerous stage of the disease with minor surgical treatments. However, this is not the case for breast cancer or colorectal cancer screening through examination of faecal occult blood.

In Bulgaria, the project BG051RO001-5.3.02-001-C0001 "Stop and Get Checked" was carried out, which was launched on 21.05.2009 and terminated on 21.10.2014. The screening tests were carried out using the screening tests specified in the Recommendation of the Council of the European Union (2003/878/EC) of 2 December 2003:

- Pap smear for detecting early signs of cervical cancer;
- mammography screening for breast cancer in women every 2 years;
- analysis for occult blood in faeces for colorectal cancer.

Unfortunately, the activities were discontinued after the completion of the project and Bulgaria is currently one of the few countries in Europe where there are no population-based screening programmes.

In conclusion, it is highly imperative to establish population-based screening programmes targeting the above-mentioned loci—cervix, mammary gland and colorectum.

State of the health system

Primary outpatient care

The problems in this sector have been discussed repeatedly, but to no effect. Ageing of staff, lack of motivation to work in remote areas, lack of postgraduate and continuing education system, reluctance to group into larger practices, etc. Gradually the specialty of General Medicine has become unappealing and unattractive, which is largely due to the pursued policy of concentrating services within hospital care and medicines. The analysis of the activities in this sector has been made above and it reveals that GP's are an indispensable resource for action in such a situation. This is particularly evident in the vaccination campaign that has been launched—the involvement of GP's has dramatically improved the success rate of the campaign.

Specialised outpatient care

The absence of a state policy to develop specialists in all specialties of medicine—and not just in those that are attractive from a financial and prestigious point of view—has led to the fact that a number of specialties with a low market share, such as infectious disease specialists, virologists, epidemiologists, pathologists, etc. are at the sanitary minimum, and some are almost extinct. This is further aggravated by the fact that the vast majority of examinations that could be done in outpatient care are being carried out in hospitals. The simplest analysis of the NHIF's expenditure over the years shows that after the promotion and prophylaxis, the primary health care and outpatient examinations are the least funded. This fact leads to an inability to fully cover pathology in outpatient settings and directs the patient flow to hospitals.

Hospital care

It is well known that Bulgaria probably leads the rankings in the highest number of hospitals per capita. Since the reforms in 2000 and especially after the ban on privatisation in this sector, the number of hospitals has doubled in the country, and this has been at the expense of private hospitals. During all these twenty years, no attempt has been made to optimise the number of hospitals in the country. This has led to a great diversity and inequality of hospitals due to the insufficient resources of the state and municipalities to maintain all the hospital structures in which they have a stake.

A number of infectious diseases wards were shut down, which had an impact on the number of infectious disease specialists in the country. It is the state, namely the Ministry of Health, which must provide specialities and structures that are not attractive and relevant in a market environment, but are of vital importance in an emergency situation.

The political propaganda in the healthcare sector does not allow to view the equality of all hospital facilities in terms of patients, i.e., equal access to all of them regardless of the type of ownership. Moreover, the attitude has been created among the population that all the problems of the system stem from the legal status of hospitals. At the beginning of the pandemic, the main focus was on three large metropolitan public hospitals, which were heavily publicised in the media. Subsequently, it turned out that a number of other hospitals, be they private, municipal or public, fully committed all their resources to tackling the pandemic. In the course of the pandemic, it turned out that much of the necessary equipment—mainly oxygen—was lacking, especially in the smaller community hospitals. Other hospitals, including private ones, adapted very quickly and provided central oxygen supply systems, which proved vital. A detailed analysis of hospital operations is provided in the relevant section of this report.

Emergency medical care

The detailed analysis of emergency care activity is presented in the relevant section of this report. It can only be added here that since 2014, a project was initiated to rebuild, reinforce and equip the emergency care, for which funds were secured from an operational programme. The project includes the establishment of emergency portals in 28 districts with the necessary equipment, the purchase of 400 ambulances and the training of around 4,000 personnel serving in the ambulance system. After interruptions, postponements and periods of complete inaction due to frequent changes of Ministers of Health, the project has not yet been completed in any of the three components. It could be assumed that if the project had achieved its objectives before the onset of the pandemic, the results might have been different and the burden on the system less.

Human resources

For years there has been talk about the reduction of medical staff and its ageing, migration and the lack of experts. It was pointed out above that unappealing specialties and such that cannot be practiced in stand-alone outpatient settings—i.e. not allowing private practice—are gradually declining and are even on the verge of extinction. Within the context of the pandemic, this has proved to be the case for infection experts, virologists, anaesthesiologists, laboratory physicians, pathologists, etc. The lack of support staff and health care experts was particularly pronounced.

Information provision

The pandemic precipitated the development of a unified information portal for COVID-19 that collects incoming current information on the status of the epidemic and provides valuable orientation for policy decision-making. During the pandemic, the long-awaited e-prescription was introduced as part of the future and long-delayed National Health Information System (NHIS). The need for such a system with an electronic patient record and all the attributes envisaged in the design of the NHIS became very apparent during the pandemic, especially with regard to epidemiological studies of the infected and the limited possibilities for follow-up of the recovered patients.

Financial provision

Over the past two decades, the initial health insurance model that was introduced in 2000 has gradually transformed from a public to a state-controlled model. The concentration of the management of public resources collected through health insurance contributions, in the hands of the state through the Ministry of Health and the Ministry of Finance, has led to recurrent practices of financing the state budget from health insurance contributions[28]. A drastic example of this is the transfer of 1.2 billion BGN from the large NHIF reserves to the state budget in 2012. In the face of a pandemic, the lack of these funds from the reserve, which were presumably collected precisely for such force majeure circumstances, became obvious, although it is not public knowledge.

Bulgaria is the country with the lowest health insurance contribution of all EU countries. It is also the country with the lowest share of GDP spent on healthcare. Along with this, half of the healthcare costs are covered by the citizens themselves. Nevertheless, a number of governments have not taken the political responsibility to solve this problem. As a result, there are serious inequalities in Bulgaria in terms of access to specialised medical care. All these problems, which have been discussed publicly over the years, have proved to be a serious obstacle to successfully tackling the pandemic, which has left a significant proportion of the hospital base decapitalised and in a deplorable state.

Pharmaceutical sector

Over the years, the largest increase in health insurance spending has been attributed to medicines and pharmaceuticals. In the course of the pandemic, the prices of some of the most widely used medicines spiked significantly, which likely affected the population's overall coping with the disease.

[28] Semerdzhiev, I.T. "The health reform in the Republic of Bulgaria. Establishing the NHIF, introduction of health insurance in the period 1997 – 2001 and subsequent development", Sofia, 2021.

Crisis management

The shortcomings in the crisis management can be classified as follows:

- lack of a communication strategy;
- lack of a systematic risk assessment;
- lack of a strategic plan to deal with an epidemic threat;
- lack of unity regarding the medical aspects of the pandemic;
- lack of standards and protocols for the treatment of the coronavirus infection;
- lack of adequate and sufficient funding from the beginning of the pandemic.

Lack of a communication strategy

The lack of a communications strategy is, in our view, at the top of the priorities of an effective crisis management of this order. The global panic, the general uncertainty about the nature of the new coronavirus, the lack of a rudimentary sense of public perceptions and the effects of an induced mass psychosis are the main reasons for the expected long-term consequences of the pandemic in terms of the psychological functioning and the full recovery from the crisis. Understandably, the people charged with this responsibility are not similarly qualified and could not have avoided some of the undesirable effects of the crisis discourse described above. However, the refusal to use ready-made expertise in this respect by organisations that offer such cannot be justified. Already on 22.01.2020, the WHO provided the Ministry of Health with guidelines for the development of a communication strategy or risk strategy (Risk Communication and Community Engagement – RCCE), which at that time remained no more than a well-wishing. On 20.11.2020 the WHO provided the MoH with Guidelines for the development of a vaccination plan, which evidently were considered in the preparation of the plan at the end of the year.

The crisis discourse is key to achieving success in containing any mass population threat situation. A basic rule in all developed safety codes and instructions is to avoid the creation of panic. In the case of the COVID-19 communication, such panic was not avoided. On the contrary, its consequences, combined with the erosion of trust in the institutions that were managing the crisis in the first place, led to a lack of confidence in the subsequent measures to exit it, including the vaccination process. This is the main reason why Bulgaria is currently lagging behind in the vaccination plan compared to a number of other countries in Europe.

Lack of a systematic risk assessment

One of the most critical shortcomings in the management of the COVID-19 crisis is the lack of a system for mass testing of infected persons with all the resources available to the health system. The uncertainty at the outset about the effectiveness of rapid antigen testing, the lack of readiness for PCR testing, the attempt to monopolize this procedure at a central level, and the highly unequal distribution of testing across the country (as seen in the data on PCR tests paid for by the NHIS) led to decision-making not based on evidence, which in turn led to an element of voluntarism and chaos in the overall response to the crisis. To this must be added the fact that the state never took over the payment of the necessary tests for suspected and infected persons, which has led to a considerable number of citizens missing out on registration and has further overburdened household budgets.

Lack of a strategic plan to deal with an epidemic threat

Bulgaria has had a National Anti-Epidemic Plan since 2009, which according to some sources was updated in 2014. However, it was not until the end of 2020 that a National Action Plan was adopted, which once again illustrates the pace at which the challenge of COVID-19 has been addressed.

Lack of unity regarding the medical aspects of the pandemic

An advisory body called the Supreme Medical Council has been constituted under the Minister of Health as early as 2001. This council is composed of representatives of all the leading specialties in medicine, of renowned and professionally proven experts. For the last ten years, this body has not been convened by any Minister of Health, and this practice has been upheld during the pandemic. As a result of the poor construction of the NOS and the resulting oppositional attitudes among other circles of the medical community, a dualism typical of the Bulgarian reality was created, which for a period of time was legitimised by the Prime Minister himself with the creation of the Medical Advisory Board. The opposition talk by various professionals further led to distrust in the institutions responsible for dealing with the crisis, with the media also playing a role in this by simply giving a platform to everyone according to their professional code. The effects on the population were again associated with an undermining of trust and a division into groups supporting one or another speaker.

Lack of standards and protocols for the treatment of the coronavirus infection

Throughout the world, the issue of treating the coronavirus infection was not solved from the very beginning of the pandemic and the hospital workers, on the basis of their clinical experience, created their own algorithms and standards for treatment. This lack of clarity resulted in complications and probably quite a few deaths due to improper treatment and approach to the disease.

Lack of adequate and sufficient funding from the beginning of the pandemic

The analysis of the orders issued by the two ministers reveals that the serious funding of hospitals and the takeover of the payment of a number of medicines by the NHIF occurred only during and after the major first peak of the pandemic in the autumn of 2020. At that time, the clinical pathways allocated to COVID-19 (39, 48 and 104), as well as two procedures, are increased to BGN 1,200, having previously been priced between BGN 700 and BGN 900. The increase is not retrospective and this remains at the expense of the medical institutions.

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Bulgaria has suffered serious losses as a result of the COVID-19 pandemic, reflected primarily in loss of human lives, deterioration of public health, anticipated mental health problems in the population, as well as economic, social and other losses that are beyond the scope of this analysis. In terms of medical losses, the unfavourable truth emerges that a significant proportion of the deaths resulted from health care problems during the pandemic. The high levels of EU-wide mortality reported at the beginning of this report illustrate the fact that the Bulgarian population entered this pandemic in a state of poor health. The figures for total, preventable and foreseeable mortality are significantly higher than the EU average. In practice, these are indicators of the effectiveness of the health system and the state of public health efforts related to prevention, health promotion and the prevention of disease. These indicators, together with the poor organisation in the management of the pandemic, are the main reason for the staggeringly high mortality rates

observed in Bulgaria during the two pandemic peaks—autumn 2020 and spring 2021.

A particularly telling fact is the difference between the incidence and mortality of COVID-19 in a comparative international perspective (part one of the report). This fact can be interpreted in two ways. The first is that although the incidence of COVID-19 among Bulgarians is within the European average, those who fall ill die much more often, which is a very poor attestation of the state of the medical care they have received. The other way of explaining this is the under-registration of people who are ill, which implies, again, that a large proportion of Bulgarian citizens were left out of the healthcare system and died at home.

The crisis in Bulgaria related to COVID-19 has been managed mostly through a political and not so much through a medical approach. Thus, no particular guilty parties can be sought - each acted according to their own convictions for the good of all. There exist objective circumstances that neither the best nor the most incompetent management can influence. This crisis has been caused to a large extent by such circumstances. The problem is that the lack of preparation, adequate funding, and a positive attitude toward public health manifests itself with devastating clarity at precisely such trying times for the entire country.

Abbreviations used:

- SARS-CoV-2 (Severe Acute Respiratory Syndrome CoronaVirus 2) – a new coronavirus 2 causing a severe acute respiratory syndrome.
- COVID-19 – CoronaVirus Infectious Disease from 2019.
- RT-real-time (q)PCR - Reverse Transcriptase-real-time-Polymerase Chain Reaction.
- NRL – National Reference Laboratory.
- NCIPD – National Centre for Infectious Parasitic Diseases.
- RHI – Regional Health Inspectorate.
- NAAT - Nucleic Acid Amplification Test.
- PCR – Polymerase Chain Reaction.
- ELISA - Enzyme-Linked ImmunoSorbent Assay.
- WHO – World Health Organisation.
- EC – European Commission.
- ECDC – European Centre for Disease Prevention and Control).
- RNA – ribonucleic acid, genetic information of SARS-CoV-2.
- DNA – deoxyribonucleic acid.
- CT – computed tomography.

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