

Montenegro

This document is a compilation of all questions, justifications, and sources used to determine the 2021 Global Health Security Index scores for Montenegro. For a category and indicator-level summary, please see the Country Profile for Montenegro.

CATEGORY 1: PREVENTING THE EMERGENCE OR RELEASE OF PATHOGENS WITH POTENTIAL FOR INTERNATIONAL CONCERN	4
1.1 Antimicrobial resistance (AMR)	4
1.2 Zoonotic disease	8
1.3 Biosecurity	14
1.4 Biosafety	21
1.5 Dual-use research and culture of responsible science	24
1.6 Immunization	27
CATEGORY 2: EARLY DETECTION AND REPORTING FOR EPIDEMICS OF POTENTIAL INTERNATIONAL CONCERN	27
2.1 Laboratory systems strength and quality	27
2.2 Laboratory supply chains	30
2.3 Real-time surveillance and reporting	31
2.4 Surveillance data accessibility and transparency	34
2.5 Case-based investigation	40
2.6 Epidemiology workforce	43
CATEGORY 3: RAPID RESPONSE TO AND MITIGATION OF THE SPREAD OF AN EPIDEMIC	45
3.1 Emergency preparedness and response planning	45
3.2 Exercising response plans	50
3.3 Emergency response operation	52
3.4 Linking public health and security authorities	55
3.5 Risk communications	56
3.6 Access to communications infrastructure	60

3.7 Trade and travel restrictions	61
-----------------------------------	----

CATEGORY 4: SUFFICIENT AND ROBUST HEALTH SECTOR TO TREAT THE SICK AND PROTECT HEALTH WORKERS 63

4.1 Health capacity in clinics, hospitals, and community care centers	63
---	----

4.2 Supply chain for health system and healthcare workers	67
---	----

4.3 Medical countermeasures and personnel deployment	72
--	----

4.4 Healthcare access	74
-----------------------	----

4.5 Communications with healthcare workers during a public health emergency	76
---	----

4.6 Infection control practices and availability of equipment	78
---	----

4.7 Capacity to test and approve new medical countermeasures	79
--	----

CATEGORY 5: COMMITMENTS TO IMPROVING NATIONAL CAPACITY, FINANCING PLANS TO ADDRESS GAPS, AND ADHERING TO GLOBAL NORMS 82

5.1 International Health Regulations (IHR) reporting compliance and disaster risk reduction	82
---	----

5.2 Cross-border agreements on public health and animal health emergency response	83
---	----

5.3 International commitments	84
-------------------------------	----

5.4 Joint External Evaluation (JEE) and Performance of Veterinary Services Pathway (PVS)	86
--	----

5.5 Financing	87
---------------	----

5.6 Commitment to sharing of genetic and biological data and specimens	91
--	----

CATEGORY 6: OVERALL RISK ENVIRONMENT AND VULNERABILITY TO BIOLOGICAL THREATS 93

6.1 Political and security risk	93
---------------------------------	----

6.2 Socio-economic resilience	97
-------------------------------	----

6.3 Infrastructure adequacy	99
-----------------------------	----

6.4 Environmental risks	100
-------------------------	-----

6.5 Public health vulnerabilities	100
-----------------------------------	-----

Category 1: Preventing the emergence or release of pathogens with potential for international concern

1.1 ANTIMICROBIAL RESISTANCE (AMR)

1.1.1 AMR surveillance, detection, and reporting

1.1.1a

Is there a national AMR plan for the surveillance, detection, and reporting of priority AMR pathogens?

Yes, there is evidence of an AMR plan, and it covers surveillance, detection, and reporting = 2, Yes, there is evidence of an AMR plan, but there is insufficient evidence that it covers surveillance, detection, and reporting = 1, No evidence of an AMR plan = 0

Current Year Score: 2

There is evidence that Montenegro has a national antimicrobial residues (AMR) plan for the surveillance, detection, and reporting of priority AMR pathogens.

The "National Programme for the Control of Antibiotic-resistant Bacteria, 2017–2021" has seven objectives: Strengthening intersectoral cooperation; improving and modernizing diagnostics (detection); improving the control of the resistance of bacteria to antibiotics; promoting the rational use of antibiotics and strengthen monitoring; strengthening surveillance of infection and control of hospital infections (surveillance); prevention of development of bacterial resistance to antibiotics in veterinary and food production; and strengthening awareness of patient safety and developing a partnership relationship (reporting). More specifically, the third objective includes improvement of the national system of monitoring, collecting, analyzing, and reporting data on resistance, thereby improving the national database and establishing links with regional databases. According to the programme, the method of monitoring AMR will be compatible with the European Antimicrobial Resistance and the Regional European Database on World Health Organization (WHO) antimicrobial resistance and, in this manner, ensure better detection and timely suppression of adverse events [1].

In addition, the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, published in March 2021 and conducted in May 2019, states that Montenegro formally approved its "National Action Plan for AMR" in March 2019, which covers "awareness raising, education, surveillance, prevention of infection and optimizing the use of antimicrobials in both human and veterinary sectors" [2]. Montenegro earns a score of 4 in the human health sector for its a centrally coordinated national AMR surveillance system, although it does not have such capacities in the animal husbandry or agricultural sectors, where its is score 2. The JEE also states, "Although there is no national programme for Infection and Prevention and Control (IPC), all health care facilities at the secondary and tertiary levels are obliged by law to adopt a program to monitor, prevent, and combat hospital infections", as well as to submit "semi-annual reports to the National Committee for Hospital Infections." No further evidence on AMR surveillance, detection, and reporting is available in the JEE [2].

[1] Government of Montenegro. Ministry of Health. 2016. "National Programme for the Control of Antibiotic-resistant Bacteria 2017–2021 (Strategija za kontrolu rezistencije bakterija na antibiotike 2017-2021)".

[<http://extwprlegs1.fao.org/docs/pdf/mne176056.pdf>]. Accessed 07 January 2021.

[2] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.1.1b

Is there a national laboratory/laboratory system which tests for priority AMR pathogens?

All 7 + 1 priority pathogens = 2 , Yes, but not all 7+1 pathogens = 1 , No = 0

Current Year Score: 1

There is evidence that Montenegro has a national laboratory system that tests for some, but not all, priority AMR pathogens.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, the Institute for Public Health (IPH) comprises four reference laboratories for influenza, measles, rubella, and AMR [1]. However, the JEE does not name any of the AMR pathogens tested [1]. The World Health Organization's (WHO) Annual Report for 2018 entitled "Central Asian and Eastern European Surveillance of Antimicrobial Resistance" (page 49, section 5.4.2) does state that Montenegro has the capacity to test for E. coli, K. pneumonia, S. aureus, S. pneumoniae, and Salmonella spp [2].

The website of the IPH and the "National Program for the Control of Antibiotic-resistant Bacteria, 2017-2021" do not provide information on which AMR pathogens can be tested for [3, 4]. The websites of the Ministry of Health and the Ministry of Agriculture and Rural Development also do not provide any additional evidence regarding testing for priority AMR pathogens [5, 6].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] World Health Organization (WHO). 2018. "Annual Report for 2018, Central Asian and Eastern European Surveillance of Antimicrobial Resistance". [<https://www.euro.who.int/en/health-topics/disease-prevention/antimicrobial-resistance/publications/2018/central-asian-and-eastern-european-surveillance-of-antimicrobial-resistance-annual-report-2018-2018>] Accessed 07 January 2021

[3] Government of Montenegro, Ministry of Health. 2016. "National Program for the Control of Antibiotic-resistant Bacteria, 2017-2021 (Strategija za kontrolu rezistencije bakterija na antibiotike 2017-2021)". [<http://extwprlegs1.fao.org/docs/pdf/mne176056.pdf>]. Accessed 07 January 2021.

[4] Institute for Public Health. Center for Medical Microbiology. [<https://www.ijzcg.me/centri/centar-za-medicinsku-mikrobiologiju/>]. Accessed 07 January 2021.

[5] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

1.1.1c

Does the government conduct environmental detection or surveillance activities (e.g., in soil, waterways) for antimicrobial residues or AMR organisms?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro conducts environmental detection or surveillance activities for antimicrobial residues (AMR) or AMR organisms.

The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, states that Montenegro formally approved its "National Action Plan for AMR" in March 2019, which covers "awareness

raising, education, surveillance, prevention of infection and optimizing the use of antimicrobials in both human and veterinary sectors" but that it does not include agriculture and environmental protection [1]. Accordingly, the country scores 2 on all AMR capacities in the JEE, despite a centrally coordinated national AMR surveillance system for human health [1].

The Montenegro Institute for Public Health (Department for Bacteriology) also notes that it conducts AMR sensitivity testing, but it does not clarify whether the test is conducted in the soil or in waterways [2]. The Agency for Natural and Environmental Protection conducts detection or surveillance activities related to soil, but there is no specific information that these activities refer to AMR or AMR organisms [3]. The website of the Ministry of Health and the national AMR plan do not have further evidence regarding detection or surveillance activities (e.g., in soil, waterways, etc.) for AMR or AMR organisms [4, 5].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Institute for Public Health (IPH), Center for Medical Microbiology. [<https://www.ijzcg.me/me/centri/centar-za-medicinsku-mikrobiologiju>]. Accessed 07 January 2021.

[3] Agency for Natural and Environmental Protection. Responsibilities. [<https://epa.org.me/djelokrug-rada/>]. Accessed 07 January 2021.

[4] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=8>]. Accessed 07 January 2021.

[5] Government of Montenegro. Ministry of Health. 2016. "National Program for the Control of Antibiotic-resistant Bacteria 2017–2021 (Strategija za kontrolu rezistencije bakterija na antibiotike 2017-2021)". [<http://extwprlegs1.fao.org/docs/pdf/mne176056.pdf>]. Accessed 07 January 2021.

1.1.2 Antimicrobial control

1.1.2a

Is there national legislation or regulation in place requiring prescriptions for antibiotic use for humans?

Yes = 2 , Yes, but there is evidence of gaps in enforcement = 1 , No = 0

Current Year Score: 2

Montenegro has national legislation or regulation in place that requires prescriptions for antibiotic use for humans.

The "Ordinance about the Form and Content of Prescriptions, Criteria for Classification of Medicines, and the Method of Prescription and Issuing of Medicines" determines the manner of prescribing and issuing medicines, including antibiotics. According to Article 15 of the Ordinance, a prescription for antibiotics is valid for three days [1]. A decision on determining the list of medicines issued by the Ministry of Health contains a list of medicines for which prescription is obligatory, including antibiotics for humans [2]. Based on the review of the websites of the Ministry of Health and Institute for Public Health (IPH), as well as media outlets, there is no evidence of gaps in enforcement. However, in Europe, Montenegro ranks fourth in the use of antibiotics [3, 4, 5]. The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, states that antibiotics are only available by prescription in the country and that Montenegro has a "national strategy for antibiotic resistance control of bacteria in place for 2017-2021 and includes such awareness-raising events as Antibiotics Awareness Week." The JEE also recommends that Montenegro develop a national guide for the rational use of antibiotics in order to reduce consumption of antimicrobial medicines in both human and veterinary sectors [6].

[1] Government of Montenegro. 2016. Ministry of Health. "Ordinance about the Form and Content of Prescriptions, Criteria for Classification of Medicines and the Method of Prescription and Issuing of Medicines (Pravilnik o obrascu i sadržini recepta, kriterijuma za klasifikaciju lijekova, kao i načinu propisivanja i izdavanja lijekova, "Službeni list Crne Gore", br. 034/15 od 03.07.2015, 036/16 od 09.06.2016)".

[https://www.fzocg.me/ckfinder/userfiles/files/folder_6/pravilnik_o_obrascu_i_sadrzini_recepta_kriterijumima_za_klasifikaciju_lijekova_kao_i_nacinu_propisivanja_i_izdavanja_lijekova.pdf]. Accessed 07 January 2021.

[2] Government of Montenegro. 2018. Ministry of Health. "Decision on Determining the List of Medicines (Odluka o utvrđivanju liste lijekova), "Službeni list Crne Gore", br. 2/2018 od 10.01.2018. godine, 23/2018 od 13.04.2018. godine i 77/2018)". [http://fzocg.me/documents/Lista_lijekova/Odluka_o_utvrivanju_Liste_lijekova_-_NOVEMBAR_2018.pdf]. Accessed 07 January 2021.

[3] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=8>]. Accessed 07 January 2021.

[4] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

[5] Vijesti. "Montenegro Ranks Fourth in the Use of Antibiotics". [<https://www.vijesti.me/vijesti/drustvo/414224/crna-gorana-cetvrtom-mjestu-po-upotrebi-antibiotika>]. Accessed 07 January 2021.

[6] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.1.2b

Is there national legislation or regulation in place requiring prescriptions for antibiotic use for animals?

Yes = 2, Yes, but there is evidence of gaps in enforcement = 1, No = 0

Current Year Score: 2

Montenegro has national legislation in place requiring prescriptions for antibiotic use for animals. The "Ordinance about the Content of Prescriptions, the Method of Prescription, and Issuing of Veterinary Medicines" determines the manner of prescribing and issuing veterinary medicines, including antibiotics [1]. A decision on determining the list of medicines issued by the Ministry of Health includes a list of medicines for which prescription is obligatory, including antibiotics for animals [2]. Based on the review of the websites of the Ministry of Health, Ministry of Agriculture, and Institute for Public Health (IPH) as well as media outlets, there is no evidence of gaps in enforcement. However, in Europe, Montenegro ranks fourth in the use of antibiotics [3, 4, 5]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, a national guide for the rational use of antibiotics must be developed to reduce consumption of antimicrobial medicines in both the human and veterinary sectors [6].

[1] Government of Montenegro, Ministry of Agriculture and Rural Development. 2013. "Ordinance about the Content of Prescriptions, the Method of Prescription and Issuing of Veterinary Medicines (Pravilnik o sadržini recepta, načinu izdavanja i propisivanju veterinarskih lijekova)". [<http://extwprlegs1.fao.org/docs/pdf/mne178761.pdf>]. Accessed 07 January 2021.

[2] Government of Montenegro, Ministry of Health. 2018. "Decision on Determining the List of Medicines (Odluka o utvrđivanju liste lijekova), "Službeni list Crne Gore", br. 2/2018 od 10.01.2018. godine, 23/2018 od 13.04.2018. godine i 77/2018)". [http://fzocg.me/documents/Lista_lijekova/Odluka_o_utvrivanju_Liste_lijekova_-_NOVEMBAR_2018.pdf]. Accessed 07 January 2021.

[3] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=8>]. Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

[6] World Health Organisation (WHO). March 17, 2021. "Joint external evaluation of IHR core capacities of Montenegro:

mission report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.2 ZOO NOTIC DISEASE

1.2.1 National planning for zoonotic diseases/pathogens

1.2.1a

Is there national legislation, plans, or equivalent strategy documents on zoonotic disease?

Yes = 1 , No = 0

Current Year Score: 1

In Montenegro, there is a national law in place for zoonotic diseases.

The law on zoonotic diseases is called the Law on Veterinary. The Law does not specify specific zoonosis, but envisages a program for monitoring, controlling, and eradication of animal diseases and zoonosis [1]. Based on the Veterinary Law the Ordinance on Surveillance of Zoonosis and Causes of Zoonosis was adopted in 2012. The purpose of this Ordinance is to ensure appropriate monitoring of zoonosis, zoonotic agents, and their resistance to antimicrobials and the appropriate epidemiological investigation of the outbreaks of foodborne diseases in order to ensure the collection of data necessary for the assessment of the sources and trends of these diseases. The Ordinance defines two groups of zoonotic diseases: "A. Zoonosis and zoonotic agents involved in monitoring: brucellosis, campylobacteriosis, listeriosis, salmonellosis (zoonotic salmonellosis), trichinellosis, echinococcosis, tuberculosis caused by mycobacterium bovis, Escherichia coli that secretes verotoxin; and B. a list of zoonoses and zoonotic agents that are monitored in accordance with the epidemiological situation: 1. viral zoonoses: infection with kalicivirus, hepatitis A virus, influenza virus, rabies, infections from viruses transmitted by arthropods; 2. bacterial zoonoses: borreliosis, botulism, leptospirosis, chlamydia, mycobacteriosis other than tuberculosis caused by mycobacterium bovis, vibriosis, jersinia; 3. parasitic zoonoses: anemia, cryptosporidiosis, cysticercosis, toxoplasmosis; and 4. other zoonoses and zoonotic agents" [2].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, Montenegro's legislative framework for surveillance, control and reporting of zoonotic and foodborne diseases is harmonized with EU legislation. The management of zoonotic diseases as part of IHR implementation covers both human and animal sectors, which share responsibility for disease detection, surveillance, and reporting. It also mentions that the country has a established multi-sectoral teams for avian influenza and flu pandemic, Ebola and rabies. [3]

[1] Directorate for Food Safety, Veterinary and Phytosanitary Affairs. 2018. "Law on Veterinary (Zakon o veterinarstvu, Sl. CG. br. 30/2012, 48/2015, 52/16 i 43/18)". [http://www.ubh.gov.me/biblioteka/sektor_2/zakonij]. Accessed 07 January 2021

[2] Directorate for Food Safety, Veterinary and Phytosanitary Affairs. 2015. "Ordinance on Surveillance of Zoonoses and Causes of Zoonoses (Pravilnik o nacinu pracenja zoonoza i uzrocnika zoonoza, Sl. CG. 7/2012)".

[<http://www.ubh.gov.me/ResourceManager/FileDownload.aspx?rid=197776&rType=2&file=59218.pdf>]. Accessed 07 January 2021.

[3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.2.1b

Is there national legislation, plans or equivalent strategy document(s) which includes measures for risk identification and reduction for zoonotic disease spillover events from animals to humans?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro has a national legislation, plans, or equivalent strategy document(s) that include measures for risk identification and reduction for zoonotic disease spillover events from animals to humans. The Law of Veterinary and the Ordinance on Surveillance of Zoonoses and Causes of Zoonoses do not prescribe the measures for risk identification and reduction for zoonotic disease spillover events from animals to humans [1, 2]. The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro does not have a reference to measures for risk identification and reduction for zoonotic disease spillover events from animals to humans. According to the report, in order to document the timeliness and efficiency of intersectoral operational mechanisms, evidence and records of joint investigation and tracking of zoonotic diseases incidents must be improved [3]. The websites of the Ministry of Health and Ministry of Agriculture do not have information about measures for risk identification and reduction for zoonotic disease spillover events from animals to humans [4, 5].

[1] Directorate for Food Safety, Veterinary and Phytosanitary Affairs. 2018. "Law on Veterinary (Zakon o veterinarstvu, Sl. CG. br. 30/2012, 48/2015, 52/16 i 43/18)". [http://www.ubh.gov.me/biblioteka/sektor_2/zakonij] Accessed 07 January 2021.

[2] Directorate for Food Safety, Veterinary and Phytosanitary Affairs. 2015. "Ordinance on Surveillance of Zoonoses and Causes of Zoonoses (Pravilnik o nacinu pracenja zoonoza i uzrocnika zoonoza, Sl. CG. 7/2012)".

[<http://www.ubh.gov.me/ResourceManager/FileDownload.aspx?rid=197776&rType=2&file=59218.pdf>]. Accessed 07 January 2021.

[3] World Health Organisation (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[4] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=8>]. Accessed 07 January 2021.

[5] Ministry of Agriculture, Forestry and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

1.2.1c

Is there national legislation, plans, or guidelines that account for the surveillance and control of multiple zoonotic pathogens of public health concern?

Yes = 1 , No = 0

Current Year Score: 1

Montenegro has a national legislation, plans, or guidelines that account for the surveillance and control of multiple zoonotic pathogens of public health concern.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, Montenegro's legislative framework for surveillance, control, and reporting of zoonotic and foodborne diseases is harmonized with EU legislation [1]. It further mentions that the country adopts a "multi-sectoral approach and coordinated surveillance systems between animal and public health sectors" for zoonosis and that there is mutual reporting and information sharing between the human and animal sectors. [1]

The Ordinance on Surveillance of Zoonosis and Causes of Zoonosis, which was adopted in 2012 based on the Law of Veterinary, defines two major and several sub-groups of zoonotic diseases, including zoonosis and zoonotic agents involved in monitoring (e.g., brucellosis, campylobacteriosis, and listeriosis) and zoonoses and zoonotic agents that are monitored in accordance with the epidemiological situation for i) viral zoonosis (e.g., hepatitis A virus, influenza virus, and rabies), ii) bacterial zoonoses (e.g., leptospirosis, chlamydia, and mycobacterium bovis), iii) parasitic zoonoses (e.g., cysticercosis and toxoplasmosis), iv) other zoonoses and zoonotic agents [2]. According to Article 8 of this Ordinance, the state authorities that are responsible for food safety (i.e., Ministry of Agriculture and Ministry of Health) are obliged to prepare and share the reports on movement and sources of zoonoses, causative agents zoonosis, and antimicrobial resistance. The template of the report on trends and sources of zoonosis, zoonotic agents, and antimicrobial resistance resources---found in Annex 2 of the Ordinance, requests, under section A---asks for details on control measures taken to reduce the incidence of zoonoses and their transmission to humans [2].

The websites of the Ministries of Health and Agriculture do not have additional information about plans that guide the control measures that must be taken [3, 4].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Directorate for Food Safety, Veterinary, and Phytosanitary Affairs. 2015. "Ordinance on Surveillance of Zoonoses and Causes of Zoonoses (Pravilnik o nacinu pracenja zoonoza i uzročnika zoonoza, Sl. CG. 7/2012)". [<http://www.ubh.gov.me/ResourceManager/FileDownload.aspx?rid=197776&rType=2&file=59218.pdf>]. Accessed 07 January 2021.

[3] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=8>]. Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

1.2.1d

Is there a department, agency, or similar unit dedicated to zoonotic disease that functions across ministries?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that Montenegro has a relevant unit dedicated to zoonotic diseases that functions across ministries.

According to Article 8 of the Ordinance on Surveillance of Zoonoses and Causes of Zoonoses, the Montenegro Directorate for Food Safety, Veterinary, and Phytosanitary Affairs, which is part of the Ministry of Agriculture and Rural Development, assesses the trends and sources of zoonoses, zoonotic agents, and resistance to antimicrobial agents and prepares reports on these [1].

The Directorate is responsible, among other things, for the implementation of activities in the field of veterinary medicine in accordance with the Mandatory Animal Health Program and other programs for controlling animal diseases and zoonoses [2]. There is no evidence on this Directorate's website to suggest that it functions inter-ministerially. Further, the websites of the Ministries of Health and Agriculture do not provide evidence of an agency or similar unit dedicated to zoonotic disease that functions across ministries [3, 4].

The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro reports that the National Infectious Diseases Commission, which is currently being established by the Ministry of Health (MoH), functions as a multisectoral working group

for infectious diseases, including zoonoses. Multisectoral teams and committees have been previously established for avian influenza and the flu pandemic in 2005, for Ebola in 2014, and a Commission for rabies set up in 2011 [5].

[1] Directorate for Food Safety, Veterinary and Phytosanitary Affairs. 2015. "Ordinance on Surveillance of Zoonoses and Causes of Zoonoses (Pravilnik o nacinu pracenja zoonoza i uzrocnika zoonoza, Sl. CG. 7/2012)".

[<http://www.ubh.gov.me/ResourceManager/FileDownload.aspx?rid=197776&rType=2&file=59218.pdf>]. Accessed 07 January 2021.

[2] Agency for Food Safety, Veterinary, and Photosanitary Affairs

[http://www.ubh.gov.me/Organizacija/Sektor_za_veterinu/nadleznosti/]. Accessed 07 January 2021.

[3] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=8>]. Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] World Health Organisation (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.2.2 Surveillance systems for zoonotic diseases/pathogens

1.2.2a

Does the country have a national mechanism (either voluntary or mandatory) for owners of livestock to conduct and report on disease surveillance to a central government agency?

Yes = 1, No = 0

Current Year Score: 1

Montenegro has a national mandatory mechanism for owners of livestock to conduct and report on disease surveillance to a central government agency. According to Article 4 of the Ordinance on the Classification of Diseases of Animals, Method of Notification, and Denotification of Animal Diseases issued by the Ministry of Agriculture: "In the event of signs of illness and/or death of the animal, the owner of the animal must notify the veterinarian service or veterinarian." The ordinance applies to all livestock and specifies that the owner can report a case over the phone or on telefax or email [1]. The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, and the websites of the Ministries of Health and Agriculture do not contain information regarding such a mechanism [2, 3, 4].

[1] Ministry of Agriculture, Forestry, and Water Management. "Ordinance on the Classification of Diseases of Animals, Method of Notification, and Denotification of Animal Diseases (Pravilnik o klasifikaciji zaraznih bolesti životinja, nacinu prijavljivanja pojave odnosno sumnje i odjavljivanja zaraznih bolesti životinja)".

[http://www.ubh.gov.me/ResourceManager/FileDownload.aspx?rid=298436&rType=2&file=Pravilnik_o_klas_na%C4%8Dinu_prijavljivanja_pojave_sumnje_i_odjavljivanja_zaraznih_bolesti_%C5%BEivot.pdf]. Accessed 07 January 2021.

[2] World Health Organisation (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/en/ministry?alphabet=lat>]. Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

1.2.2b

Is there legislation and/or regulations that safeguard the confidentiality of information generated through surveillance activities for animals (for owners)?

Yes = 1, No = 0

Current Year Score: 0

Montenegro does not have a law that safeguards the confidentiality of information generated through surveillance activities for animals (for owners). The Law on Protection of Personal Data guarantees protection to every person, regardless of nationality, residence, race, etc. but it does not refer to surveillance activities for animals (for owners) [1]. The Law on Veterinary and the website of the Ministries of Health and Agriculture do not contain information related to surveillance activities for animals (for owners) [2, 3, 4]. Moreover, there is no information regarding this in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021 [5].

[1] Parliament of Montenegro. 2009. "Law on Protection of Personal Data (Zakon o zaštiti podataka ličnosti, Sl. CG. br. 79/08 od 23.12.2008, 70/09 od 21.10.2009, 44/12 od 09.08.2012)". [<http://www.azlp.me/docs/zajednicka/zakoni/zakon-o-zastiti-podataka-o-licnosti.pdf>]. Accessed 07 January 2021.

[2] Directorate for Food Safety, Veterinary, and Phytosanitary Affairs. 2018. "Law on Veterinary (Zakon o veterinarstvu, Sl. CG. br. 30/2012, 48/2015, 52/16 i 43/18)". [http://www.ubh.gov.me/biblioteka/sektor_2/zakoni]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/en/ministry?alphabet=lat>]. Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.2.2c

Does the country conduct surveillance of zoonotic disease in wildlife (e.g., wild animals, insects, other disease vectors)?

Yes = 1, No = 0

Current Year Score: 1

Montenegro conducts surveillance of zoonotic disease in wildlife (e.g., wild animals, insects, other disease vectors, etc.). The Directorate for Food Safety, Veterinary, and Phytosanitary Affairs of the Ministry of Agriculture implements measures for early detection and prevention of emergence, control, monitoring, and investigation of the emergence of dangerous animal diseases, including zoonoses. The Directorate for Food Safety, Veterinary, and Phytosanitary Affairs is responsible for the implementation of the program of compulsory animal health protection and other programs for the control of animal diseases and zoonoses [1]. A few diseases in wildlife reported in the "Report on the Work and State of Affairs in the Administrative Fields of the Ministry of Agriculture and Rural Development and Associated Agencies for 2018" are trihinelosis of wild boars and American plague of bee nests [2]. In addition, the Directorate for Food Safety, Veterinary, and Phytosanitary Affairs publishes monthly reports on animal diseases. These reports (e.g., report for February 2019) also include statistics on disease surveillance in wildlife [3]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, the management of zoonotic diseases as part of IHR implementation covers both human and animal sectors, which share responsibility for disease detection, surveillance, and reporting. The JEE also mentions that the "Program of Food and Feed Safety Measures monitors *Listeria monocytogenes*, campylobacteriosis and their causes, salmonella in food, and *Escherichia coli* (in shells), among others" [4].

- [1] Directorate for Food Safety, Veterinary, and Phytosanitary Affairs. "Responsibilities". [http://www.ubh.gov.me/Organizacija/Sektor_za_veterinu/nadleznosti/]. Accessed 07 January 2021.
- [2] Ministry of Agriculture and Rural Development. 2019. "Report on the Work and State of Affairs in the Administrative Fields of the Ministry of Agriculture and Rural Development and Associated Agencies for 2018 (Izveštaj o radu i stanju u upravnim oblastima Ministarstva poljoprivrede i ruralnog razvoja i organa u sastavu za 2018. godinu)". [https://www.gov.me/biblioteka/izvjestaji?pagerindex=18&AccessibilityFontSize=150]. Accessed 07 January 2021.
- [3] Directorate for Food Safety, Veterinary, and Phytosanitary Affairs. Monthly Reports on Animal Diseases. [http://www.ubh.gov.me/rubrike/mjesecni-izvjestaji]. Accessed 07 January 2021.
- [4] World Health Organisation (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.

1.2.3 International reporting of animal disease outbreaks

1.2.3a

Has the country submitted a report to OIE on the incidence of human cases of zoonotic disease for the last calendar year?

Yes = 1, No = 0

Current Year Score: 0

2019

OIE WAHIS database

1.2.4 Animal health workforce

1.2.4a

Number of veterinarians per 100,000 people

Input number

Current Year Score: 38.26

2018

OIE WAHIS database

1.2.4b

Number of veterinary para-professionals per 100,000 people

Input number

Current Year Score: 12.7

2018

OIE WAHIS database

1.2.5 Private sector and zoonotic

1.2.5a

Does the national plan on zoonotic disease or other legislation, regulations, or plans include mechanisms for working with the private sector in controlling or responding to zoonoses?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro's national plan on zoonotic disease or other legislation, regulations, or plans include mechanisms for working with the private sector in controlling or responding to zoonoses. The Law on Veterinary and Ordinance on Surveillance of Zoonoses and Causes of Zoonoses do not envisage cooperation with the private sector in controlling or responding to zoonoses. [1, 2] In addition, the Report on the Work and State of Affairs in the Administrative Fields of the Ministry of Agriculture and Rural Development and associated agencies for 2018 does not refer to cooperation with the private sector in controlling or responding to zoonoses [3]. The websites of the Ministries of Health and Agriculture do not have information about mechanisms for working with the private sector in controlling or responding to zoonoses [4, 5]. The Joint External Evaluation of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, does not mention any mechanisms for working with the private sector in controlling or responding to zoonoses. [6]

[1] Parliament of Montenegro. 2018. "Law on Veterinary (Zakon o veterinarstvu, Sl. CG 30/2012 48/2015 i 43/18)". [<http://www.ubh.gov.me/biblioteka/zakoni>]. Accessed 07 January 2021.

[2] Directorate for Food Safety, Veterinary, and Phytosanitary Affairs. 2015. "Ordinance on Surveillance of Zoonoses and Causes of Zoonoses (Pravilnik o nacinu pracenja zoonoza i uzrocnika zoonoza, Sl. CG. 7/2012)". [<http://www.ubh.gov.me/ResourceManager/FileDownload.aspx?rid=197776&rType=2&file=59218.pdf>]. Accessed 07 January 2021.

[3] Ministry of Agriculture and Rural Development. 2019. "Report on the Work and State of Affairs in the Administrative Fields of the Ministry of Agriculture and Rural Development and Associated Agencies for 2018 (Izveštaj o radu i stanju u upravnim oblastima Ministarstva poljoprivrede i ruralnog razvoja i organa u sastavu za 2018. godinu)". [<https://www.gov.me/biblioteka/izvjestaji?pagerindex=18&AccessibilityFontSize=150>]. Accessed 07 January 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/en/ministry?alphabet=lat>]. Accessed 07 January 2021.

[5] Ministry of Agriculture, Forestry and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.3 BIOSECURITY

1.3.1 Whole-of- government biosecurity systems

1.3.1a

Does the country have in place a record, updated within the past five years, of the facilities in which especially dangerous pathogens and toxins are stored or processed, including details on inventories and inventory management systems of those facilities?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence of a consolidated record, updated within the past five years, of facilities that store or process especially dangerous pathogens and toxins, including details on inventories and inventory management systems of such facilities. The Montenegro Central Registry of Business Entities, the Ministries of Agriculture, Defense, Health, and Science, the Institute for Public Health, Center for Ecotoxicological Research, and the VERTIC database do not contain information about monitoring facilities that have dangerous pathogens and toxins [1, 2, 3, 4, 5, 6, 7, 8]. Although Montenegro has submitted reports on confidence building measures (CBM) for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [9]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, a process has been initiated to monitor and develop up-to-date records and inventories of pathogens within facilities that preserve or process dangerous pathogens, toxins, and cultivated organisms. Pathogen collections are only stored in certain laboratories, although no list of pathogens of concern exists at a central level [10].

- [1] Central Registry of Business Entities. [<http://www.pretraga.crps.me:8083/>]. Accessed 07 January 2021.
- [2] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [3] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [6] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.
- [7] Center for Ecotoxicological Research. [http://eng.ceti.me/?page_id=1195]. Accessed 07 January 2021.
- [8] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.
- [9] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.
- [10] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.3.1b

Does the country have in place legislation and/or regulations related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro has in place legislation and/or regulations related to biosecurity that address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed.

The Ministries of Agriculture, Defense, Health, Science and Institute for Public Health do not have any information about biosecurity legislation [1, 2, 3, 4, 5]. There are also no laws on biosecurity mentioned in the VERTIC legislation database [6]. Although Montenegro has submitted reports on confidence building measures (CBM) for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, there is partial legislation on biosafety and biosecurity that require more attention and further improvement; moreover, some, if not all, elements of a comprehensive biosecurity and biosafety system are in place. Further, there are no

common biosafety and biosecurity requirements or licensing conditions for all laboratories. There is no defined policy of using diagnostic tests to eliminate the need for cultivation of dangerous pathogens. The JEE also mentions that "procedures are in place for access control and other security measures to secure laboratories, in accordance with requirements of the International Organization for Standardization (ISO) 9001 and ISO 17025" and that the "at the national level, the army of Montenegro has the capacity to manage emergency biological situations"; however, it does not mention anything about physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities [8].

- [1] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [2] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.
- [6] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.
- [7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.
- [8] World Health Organization (WHO). March 17, 2021. "Joint external evaluation of IHR core capacities of Montenegro: mission report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.3.1c

Is there an established agency (or agencies) responsible for the enforcement of biosecurity legislation and regulations?

Yes = 1 , No = 0

Current Year Score: 0

Montenegro does not have in place legislation and/or regulations related to biosecurity and, therefore, does not have an established agency (or agencies) responsible for the enforcement of biosecurity legislation and regulations. The Ministries of Agriculture, Defense, Health, and Science, the Institute for Public Health, the Accreditation Body of Montenegro (as a body responsible for accreditation of different facilities and laboratories), and the VERTIC database do not have any information about biosecurity legislation and related enforcement agencies [1, 2, 3, 4, 5, 6, 7]. Although Montenegro has submitted confidence building measures (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [8]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, the Ministry of Health is responsible for issuing "approvals for the transport of infectious substances beyond the borders of the country, and personnel from the Centre for Medical Microbiology have attended WHO training for the transport of infectious substances and patient specimens." The JEE also states that basic biosecurity and biosafety is provided by the Faculty of Medicine in the country. However, as per the JEE report, there is no evidence of an established agency in charge of biosecurity enforcement [9].

- [1] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [2] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.
- [6] Accreditation Body of Montenegro. [<http://www.akreditacija.me/en/index.php#>]. Accessed 07 January 2021.
- [7] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

[8] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [https://bwc-ecbm.unog.ch/state/montenegro]. Accessed 07 January 2021.

[9] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.

1.3.1d

Is there public evidence that shows that the country has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities?

Yes = 1 , No = 0

Current Year Score: 0

There is no public evidence that shows that Montenegro has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities. The Ministries of Agriculture, Defense, Health, and Science, as well as the Institute for Public Health and the VERTIC database do not have public evidence that shows that Montenegro has taken actions to consolidate its inventory of dangerous pathogens into a minimum number of facilities [1, 2, 3, 4, 5, 6]. Although Montenegro has submitted confidence building measures (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, Montenegro has initiated a process "to monitor and develop up-to-date records and inventories of pathogens within facilities that preserve or process dangerous pathogens, toxins and cultivated organisms," although only a few laboratories are used to store pathogens of concern. However, there is no evidence that Montenegro has attempted to consolidate its inventories in the JEE [8].

[1] Ministry of Agriculture, Forestry, and Water Management. [https://mpr.gov.me/ministarstvo]. Accessed 07 January 2021.

[2] Ministry of Defense. [http://www.mod.gov.me/ministarstvo]. Accessed 07 January 2021.

[3] Ministry of Health. [http://www.mzd.gov.me/ministarstvo]. Accessed 07 January 2021.

[4] Ministry of Science. [http://www.mna.gov.me/ministarstvo]. Accessed 07 January 2021.

[5] Institute for Public Health. [https://www.ijzcg.me/]. Accessed 07 January 2021.

[6] VERTIC database. Montenegro. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/]. Accessed 07 January 2021.

[7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [https://bwc-ecbm.unog.ch/state/montenegro] Accessed 07 January 2021.

[8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.

1.3.1e

Is there public evidence of in-country capacity to conduct Polymerase Chain Reaction (PCR)-based diagnostic testing for anthrax and/or Ebola, which would preclude culturing a live pathogen?

Yes = 1 , No = 0

Current Year Score: 0

There is no public evidence of in-country capacity to conduct polymerase chain reaction (PCR)-based diagnostic testing for anthrax and/or Ebola, which would preclude culturing a live pathogen. Montenegro has a well-developed network of institutions that deal with infectious diseases. However, the websites of the Ministries of Defence, Health, and Agriculture;

the Institute of Public Health; the Clinic for Infectious Diseases; and the VERTIC database do not contain any information regarding PCR-based diagnostic for anthrax and/or Ebola [1, 2, 3, 4, 5, 6, 7]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, the national laboratory system can conduct a PCR test for influenza, but there is no mention of such PCR diagnostics for anthrax and Ebola in the report. The JEE also states that "Procedures are in place to manage cases of priority illnesses that tend to turn into epidemics such as Ebola virus disease, pandemic influenza or vaccine-preventable diseases," but does not mention any diagnostic testing for anthrax or Ebola [8].

[1] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Ministry of Defence. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Clinical Center of Montenegro. Clinic for Infectious Diseases. [<http://www.kccg.me/klinike-i-centri/klinike/klinika-za-infektivne-bolesti/>]. Accessed 07 January 2021.

[5] Institute for Public Health of Montenegro. Center for Medical Microbiology. [<https://www.ijzcg.me/me/centri/centar-za-medicinsku-mikrobiologiju>]. Accessed 07 January 2021.

[6] Institute for Public Health of Montenegro. Center for the Control and Prevention of Infectious Diseases. [<https://www.ijzcg.me/me/centri/centar-za-kontrolu-i-prevenciju-zaraznih-bolesti>]. Accessed 07 January 2021.

[7] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

[8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.3.2 Biosecurity training and practices

1.3.2a

Does the country require biosecurity training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro has a requirement for biosecurity training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential.

The Montenegro Health Development Strategy has envisaged the importance of capacity development; however, there is no reference to specific training programs [1]. The Annual Program for Health Protection does not have information about biosecurity training [2]. Further, the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, does not include a national training program on biosafety and biosecurity in Montenegro, although basic training is provided in the Faculty of Medicine. The personnel in most facilities, including those that preserve or work with dangerous pathogens and toxins, receive information and training on biosafety and biosecurity locally. However, there are no national records of who has undergone training [3].

The websites of relevant institutions, such as the Ministry of Health, Institute for Public Health, the Ministry of Defense, and the Ministry of Agriculture, do not contain information on biosecurity training [4, 5, 6, 7]. There is no evidence of the same in

the VERTIC BWC legislation database [8]. Although Montenegro has submitted confidence building measures (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [9].

- [1] Ministry of Health. 2003. "Montenegro Health Development Strategy (Strategija razvoja zdravstva Crne Gore). [https://mzd.gov.me/rubrike/strategija-razvoja-zdravstva-crne-gore?alphabet=lat]. Accessed 07 January 2021.
- [2] Montenegro Health Insurance Fund and Institute for Public Health. 2018. "Programme for Health Protection in Montenegro for 2018/2019 (Program zdravstvene zaštite u Crnoj Gori za 2018/2019. godinu)." [http://fzocg.me/Administracija/Documents/1560854340program_zdravstvene_zastite_za_2018-19.pdf]. Accessed 07 January 2021.
- [3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.
- [4] Institute for Public Health of Montenegro, Center for Science and Education. [https://www.ijzcg.me/me/centri/centar-za-nauku-i-edukaciju]. Accessed 07 January 2021.
- [5] Ministry of Agriculture, Forestry, and Water Management. [https://mpr.gov.me/ministarstvo]. Accessed 07 January 2021.
- [6] Ministry of Defense. [http://www.mod.gov.me/ministarstvo]. Accessed 07 January 2021.
- [7] Ministry of Health. [http://www.mzd.gov.me/ministarstvo]. Accessed 07 January 2021.
- [8] VERTIC database. Montenegro. [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/]. Accessed 07 January 2021.
- [9] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [https://bwc-ecbm.unog.ch/state/montenegro]. Accessed 07 January 2021.

1.3.3 Personnel vetting: regulating access to sensitive locations

1.3.3a

Do regulations or licensing conditions specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to the following checks: drug testing, background checks, and psychological or mental fitness checks?

Personnel are subject to all three of these checks = 3, Personnel are subject to two of these checks = 2, Personnel are subject to one of these checks = 1, Personnel are not subject to any of these checks = 0

Current Year Score: 1

In Montenegro, relevant regulations specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to psychological checks. The Ordinance on the Jobs with Special Conditions of Work and Conditions for Employees Working on These Positions regulates that employees working in positions with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential (i.e., Article 2, points 11–13) are subject to psychological checks [1]. Although Montenegro has submitted confidence-building measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [2]. The Joint External Evaluation (JEE) of IHR core capacities of Montenegro does not contain evidence on this [3].

- [1] Ministry of Labour and Social Affairs and Ministry of Health. 2016. "Ordinance on the Jobs with Special Conditions of Work and Conditions for Employees Working in These Positions ("Pravilnik o poslovima sa posebnim uslovima rada i uslovima koje treba da ispuni zaposleni za rad na tim poslovima, Broj: 170-64/16-6). [http://www.uznr.me/images/2018/regulativa/Pravilnik-o-poslovima-sa-posebnim-uslovima-rada-i-uslovima-koje-treba-da-ispuni-zaposleni-za-rad-na-tim-poslovima-70-16.pdf]. Accessed 07 January 2021.
- [2] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro".

[<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

[3] World Health Organisation (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.3.4 Transportation security

1.3.4a

Does the country have publicly available information on national regulations on the safe and secure transport of infectious substances (specifically including Categories A and B)?

Yes = 1 , No = 0

Current Year Score: 1

Montenegro has publicly available information on national regulations on the safe and secure transport of infectious substances (specifically including Categories A and B). The "Law on the Transport of Dangerous Goods" regulates all modes of transportation (Article 1) and covers areas such as obligations of participants as well as recipients in the transport of dangerous goods, packaging and labelling rules, education and training of personnel, and supervision of law enforcement [1]. According to Article 3 of the law, infectious substances are listed as a category under dangerous goods (Class 6.2). This law follows the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (e.g., security measures in transportation, education of employees, obligations of operators, etc.) [1]. Further, Montenegro is one of the 40 signatory parties of the ADR [2]. The ADR includes detailed rules on the transport of Categories A and B infectious substances [3]. Although Montenegro has submitted confidence-building measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [4].

[1] Parliament of Montenegro. 2018. "Law on the Transport of Dangerous Goods (Zakon o prevozu opasnih materija, Sl. CG, 33/2014 i 13/2018)". [<https://www.paragraf.me/propisi-crngore/zakon-o-prevozu-opasnih-materija.html>]. Accessed 07 January 2021.

[2] Safety ADR. Dangerous Goods APP. [<https://www.safetyadr.com/>]. Accessed 07 January 2021

[3] United Nations. 2016. "The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)". [http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2017/ADR2017E_web.pdf]. Accessed 07 January 2021.

[4] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

1.3.5 Cross-border transfer and end-user screening

1.3.5a

Is there legislation and/or regulations in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro has a national legislation in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential. The websites of relevant institutions, such as Ministries of Defense, Interior, Health, Agriculture and the Institute for Public Health do not have

information about overseeing the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential [1, 2, 3, 4, 5]. In 2011, Montenegro adopted the Law on Ratification of Rotterdam Convention on the Prior Informed Consent Procedures for Certain Hazardous Chemicals and Pesticides in International Trade. The objective of this Convention is to promote shared responsibility and cooperative efforts among parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use. The list of substances that this Law applies to does not include especially dangerous pathogens, toxins, and pathogens with pandemic potential [6]. Further, the Law on the Transport of Dangerous Goods, which also includes infectious substances (Class 6.2), does not include provisions for cross-border transfer and end-user screening of especially dangerous pathogens, except specifying that the holder of the permit for the transport of dangerous goods is obliged—at least 24 hours before the commencement of the transport—to notify the ministry or the administrative authority in charge of police affairs at the border crossing through which the dangerous goods are transported [7]. Further, the VERTIC Legislation database does not list any legislation that oversees the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential [8]. Although Montenegro has submitted confidence building measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [9]. The Joint External Evaluation (JEE) of IHR core capacities of Montenegro does not contain evidence on this [10].

[1] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Ministry of Interior. Documents. [<http://www.mup.gov.me/upravapolicije/biblioteka/pravilnici>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<http://www.ijzcg.me/>]. Accessed 07 January 2021.

[6] Parliament of Montenegro. 2011. "Law on Ratification of Rotterdam Convention on the Prior Informed Consent Procedures for Certain Hazardous Chemicals and Pesticides in International Trade (Zakon o potvrđivanju Roterdamske konvencije o postupku davanja saglasnosti na osnovu prethodnog obaveštenja za određene opasne hemikalije i pesticide u međunarodnoj trgovini)". [http://www.podaci.net/_gCGO/propis/Roterdska_konvencija_o/K-pdsopo01v1103.html]. Accessed 07 January 2021.

[7] Parliament of Montenegro. 2018. "Law on the Transport of Dangerous Goods (Zakon o prevozu opasnih materija, Sl. CG, 33/2014 i 13/2018)". [<https://www.paragraf.me/propisi-crngore/zakon-o-prevozu-opasnih-materija.html>]. Accessed 07 January 2021.

[8] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

[9] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

[10] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.4 BIOSAFETY

1.4.1 Whole-of-government biosafety systems

1.4.1a

Does the country have in place national biosafety legislation and/or regulations?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro has a national biosafety legislation in place. The Law on Safety and Health at Work also generally regulates protection from biological substances that are used in the work or present in the working environment, as well as provides preventive measures, risk assessment, specific protection measures, written notices, and instructions [1]. There is no additional information on the national biosafety legislation on the websites of the Ministries of Health and Agriculture and Institute for Public Health, as well as VERTIC database [2, 3, 4, 5]. Although Montenegro has submitted confidence-building measures (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [6]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, Montenegro has partial legislation on biosafety and biosecurity, which requires greater attention and further improvement. The JEE also states that a multisectoral system for biosafety and biosecurity is not adequately developed and that "a risk-based approach is not in place for classifying frontline diagnostics for Risk Group 4 microorganisms". No further evidence of the legislation and what it encompasses is provided in the JEE [7].

[1] Parliament of Montenegro. 2014. "Law on Safety and Health at Work (Zakon o zaštiti i zdravlju na radu, Sl. CG 034/14)". [http://www.privrednakomora.me/sites/pkcg.org/files/multimedia/gallery/files/2012/09/zakon_o_zastiti_i_zdravlju_na_radu.pdf]. Accessed 07 January 2021.

[2] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

[5] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

[6] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

[7] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.4.1b

Is there an established agency responsible for the enforcement of biosafety legislation and regulations?

Yes = 1, No = 0

Current Year Score: 0

Montenegro does not have an established agency responsible for the enforcement of biosafety legislation nor does it have in place any national biosafety legislation. The Law on Safety and Health at Work also regulates protection from biological substances that are used in the work or present in the working environment, as well as preventive measures, risk assessment, specific protection measures, written notices, and instructions [1]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, Montenegro has partial legislation on biosafety and biosecurity, which requires greater attention and further improvement. The JEE also states that the Ministry of Health is in charge of issuing transportation approvals for pathogens of concern, and the Faculty of Medicine provides basic biosafety and biosecurity trainings, but does not specify whether an established agency responsible for biosafety exists within the country [2]. Further, the websites of the Ministries of Health and Agriculture, Institute for Public Health, and VERTIC database provide no additional information about national biosafety legislation [3, 4, 5, 6]. Although Montenegro has submitted confidence building measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7].

- [1] Parliament of Montenegro. 2014. "Law on Safety and Health at Work". [http://www.privrednakomora.me/sites/pkcg.org/files/multimedia/gallery/files/2012/09/zakon_o_zastiti_i_zdravlju_na_radu.pdf]. Accessed 07 January 2021.
- [2] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.
- [3] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.
- [6] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.
- [7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

1.4.2 Biosafety training and practices

1.4.2a

Does the country require biosafety training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?

Yes = 1, No = 0

Current Year Score: 0

There is no public evidence that Montenegro requires biosafety training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. The websites of the Ministry of Health, Agriculture and Rural Development, and Science; the Institute for Public Health; and the VERTIC database do not provide information about biosafety training [1, 2, 3, 4, 5]. Further, Article 5 of the Law on Safety and Health at Work regulates that education in the field of occupational health and safety is an integral part of the general and professional training on all types and levels of education of employees, but there is no specific evidence of biosafety training [6]. Although Montenegro has submitted confidence-building measures (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, there is no national training programme on biosafety and biosecurity in Montenegro, although basic training is provided in the Faculty of Medicine. The JEE states that the "personnel in most facilities, including those that preserve or work with dangerous pathogens and toxins, receive information and training on biosafety and biosecurity locally" [8].

- [1] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [2] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [3] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.
- [5] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.
- [6] Parliament of Montenegro. 2014. "Law on Safety and Health at Work (Zakon o zaštiti i zdravlju na radu, Sl. CG 034/14)". [http://www.privrednakomora.me/sites/pkcg.org/files/multimedia/gallery/files/2012/09/zakon_o_zastiti_i_zdravlju_na_radu.pdf]. Accessed 07 January 2021.
- [7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro".

[<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

[8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.5 DUAL-USE RESEARCH AND CULTURE OF RESPONSIBLE SCIENCE

1.5.1 Oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research

1.5.1a

Is there publicly available evidence that the country has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that Montenegro has conducted an assessment to determine whether ongoing research is being conducted on especially dangerous pathogens, toxins, pathogens with pandemic potential, and/or other dual-use research. The websites of the Ministry of Health, Ministry of Agriculture and Rural Development, Ministry of Defense, Ministry of Science, Institute for Public Health, and the VERTIC database provide no evidence about such an assessment [1, 2, 3, 4, 5, 6]. Further, although Montenegro has submitted confidence-building measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7]. There is no evidence of the same given in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, as it mentions that current legislation on biosafety and biosecurity does not include dual use research of concern [8].

[1] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<http://www.ijzcg.me/>]. Accessed 07 January 2021.

[6] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

[7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

[8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.5.1b

Is there legislation and/or regulation requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

In Montenegro, there is no national policy requiring the oversight of dual-use research, such as research with especially dangerous pathogens, toxins, and/or pathogens with pandemic potential. The websites of the Ministries of Agriculture, Defense, Health and Science provide no information about oversight of dual-use research, such as research with especially dangerous pathogens, toxins, and/or pathogens with pandemic potential [1, 2, 3, 4]. Further, the Law on Foreign Trade of Military Equipment and Goods of Double Purpose does not regulate oversight of dual use research [5]. In addition, the VERTIC database does not have any additional legislation related to the oversight of dual-use research [6]. Although Montenegro has submitted confidence-building measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7]. Moreover, no evidence of this is provided in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, as it mentions that current legislation on biosafety and biosecurity does not include dual use research of concern [8].

[1] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Parliament of Montenegro. 2009. "Law on Foreign Trade of Military Equipment and Goods of Double Purpose (Zakon o spoljnoj trgovini naoružanjem, vojnom opremom i robom dvostruke namjene)". [<http://www.seesac.org/f/docs/Montenegro-1/Act-on-Foreign-Trade-in-Weapons-Military-Equipment-and-Dual-Use-Items-2008-B.pdf>]. Accessed 07 January 2021.

[6] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

[7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.

[8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.5.1c

Is there an agency responsible for oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1, No = 0

Current Year Score: 0

In Montenegro, there is no evidence of an agency responsible for oversight of research with especially dangerous pathogens, pathogens with pandemic potential, and/or other dual-use research. Although the Law on Foreign Trade of Military Equipment and Goods of Double Purpose sets licensing conditions for those handling dual use materials, there is no mention of an agency responsible for oversight of research [1]. The websites of the Ministry of Health, Ministry of Agriculture and Rural Development, Ministry of Defense, Ministry of Science, Institute for Public Health and VERTIC database do not provide information about an agency responsible for oversight of dual use research [2, 3, 4, 5, 6]. Although Montenegro has submitted Confidence Building Measure (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [7]. Moreover, there is no evidence of this in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, as it mentions that current legislation on biosafety and biosecurity does not include dual use research of concern. The JEE also does not mention any agency in charge of biosecurity and biosafety enforcement in the country [8].

[1] Parliament of Montenegro. 2009. "Law on Foreign Trade of Military Equipment and Goods of Double Purpose (Zakon o spoljnoj trgovini naoružanjem, vojnom opremom i robom dvostruke namjene)". [<http://www.seesac.org/f/docs/Montenegro-1/Act-on-Foreign-Trade-in-Weapons-Military-Equipment-and-Dual-Use-Items-2008-B.pdf>]. Accessed 07 January 2021.

- [2] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [3] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [6] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.
- [7] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports—Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.
- [8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.5.2 Screening guidance for providers of genetic material

1.5.2a

Is there legislation and/or regulation requiring the screening of synthesized DNA (deoxyribonucleic acid) against lists of known pathogens and toxins before it is sold?

Yes = 1, No = 0

Current Year Score: 0

There is no public evidence of a national legislation or policy addressing the screening of synthesized DNA before it is sold in Montenegro. The Ministry of Agriculture, Ministry of Defense, Ministry of Health, Ministry of Science, and Ministry of Transport and Maritime Affairs have not issued regulation, policy, or other guidelines regarding the sale of synthesized DNA [1, 2, 3, 4, 5]. In addition, relevant legislation, such as the Law on Protection of Genetic Data and Law on Use of Biological Samples, do not require the screening of synthesized DNA before it is sold [6, 7]. Further, although Montenegro has submitted confidence-building measures (CBM) reports for 2018, 2019, and 2020, the submission records are locked and cannot be accessed [8]. Moreover, the VERTIC database does not contain additional information about a national legislation or policy addressing the screening of synthesized DNA before it is sold [9]. The Joint External Evaluation (JEE) of IHR core capacities of Montenegro does not provide evidence of a national legislation or policy that addresses the screening of synthesized DNA before it is sold [10].

- [1] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [2] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [4] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Ministry of Transport and Maritime Affairs. [<http://www.minsaob.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [6] Parliament of Montenegro. 2011. "Law on Protection of Genetic Data (Zakon o zaštiti genetičkih podataka, Sl. CG 025/10, 040/11)". [<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=275592&rType=2&file=Zakon%20o%20zastiti%20genetic%20podataka.pdf&alphabet=cyr>]. Accessed 07 January 2021.
- [7] Parliament of Montenegro. 2010. "Law on Use of Biological Samples (Zakon o uzimanju i korišćenju bioloških uzoraka, Sl. CG 14/2010)". [http://www.podaci.net/_gCGO/propis/Zakon_o_uzimanju/Z-ukbuzo04v1014-1140.html]. Accessed 07 January 2021.
- [8] United Nations (UN). Biological Weapons Convention. 2019. "Confidence Building Measures Reports - Montenegro". [<https://bwc-ecbm.unog.ch/state/montenegro>]. Accessed 07 January 2021.
- [9] VERTIC database. Montenegro. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed 07 January 2021.

database/m/]. Accessed 07 January 2021.

[10] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

1.6 IMMUNIZATION

1.6.1 Vaccination rates

1.6.1a

Immunization rate (measles/MCV2)

Immunization rate (measles/MCV2), 95% or greater = 2, 80-94.9% = 1, Less than 80%, or no data = 0

Current Year Score: 1

2019

World Health Organization

1.6.1b

Are official foot-and-mouth disease (FMD) vaccination figures for livestock publicly available through the OIE database?

Yes = 1, No = 0

Current Year Score: 1

2020

OIE WAHIS database

Category 2: Early detection and reporting for epidemics of potential international concern

2.1 LABORATORY SYSTEMS STRENGTH AND QUALITY

2.1.1 Laboratory testing for detection of priority diseases

2.1.1a

Does the national laboratory system have the capacity to conduct diagnostic tests for at least 5 of the 10 WHO-defined core tests?

Evidence they can conduct 5 of the 10 core tests and these tests are named = 2, Evidence they can conduct 5 of the 10 core tests and the tests are not named = 1, No evidence they can conduct 5 of the 10 core tests = 0

Current Year Score: 2

In Montenegro, the national laboratory system has the capacity to conduct diagnostic tests for at least 5 of the 10 core tests defined by the World Health Organization (WHO) and the tests are named. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, the national laboratory system is able to conduct 5 out of 10 of the core WHO-defined tests, including polymerase chain reaction (PCR) for influenza, serology for HIV, microscopy for M. tuberculosis, culture for Salmonella enteritidis serovar Typhi, and rapid test for Plasmodium spp. [1]. The websites of the Ministry of Health and Institute for Public Health do not have information about the WHO-defined core tests. [2, 3].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>] Accessed 07 January 2021.

[3] Institute for Public Health. [<http://www.ijzcg.me/>] Accessed 07 January 2021.

2.1.1b

Is there a national plan, strategy or similar document for conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing?

Yes, there is evidence of a plan, and it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 2, Yes, there is evidence of a plan, but there is insufficient evidence that it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 1, No evidence of a plan = 0

Current Year Score: 0

There is no evidence that Montenegro has a national plan, strategy, or similar document for conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing. The Law on the Protection of the Population from Infectious Diseases and websites of the Ministry of Health and Institute for Public health do not provide information about conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing [1, 2, 3]. Montenegro has a COVID-19 specific testing strategy. The COVID-19 Preparedness and Response Plan, that was adopted in March 2020, describes how Montenegro—in cooperation with the WHO and other partners—managed its response to COVID-19 and contributed to the United Nations (UN) Strategic Preparedness and Response Plan 2019; however, there is no information on scaling capacity for testing or goals defined for it [4].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

[4] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

2.1.2 Laboratory quality systems

2.1.2a

Is there a national laboratory that serves as a reference facility which is accredited (e.g., International Organization for Standardization [ISO] 15189:2003, U.S. Clinical Laboratory Improvement Amendments [CLIA])?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro has a national laboratory that serves as a reference facility that is accredited. The Institute for Public Health serves as the national laboratory for the country and houses four reference laboratories within it— influenza, measles, rubella, and antimicrobial residues (AMR) [1, 2]. The Institute is accredited by the Accreditation Body in accordance with Standard: MEST EN ISO/IEC 17025:2011. However, this accreditation is issued for testing of microbiological testing of water and foodstuffs; physical chemical analysis of water, sediment, foodstuffs, and consumer goods; physical chemical testing of wine; and testing of environmental noise. The scope of microbiology testing includes salmonella spp., Escherichia coli., Enterobacteriaceae, Staphylococcus aureus, etc. [3, 4]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, procedures are in place for access control and other security measures to secure laboratories in accordance with requirements of the International Organization for Standardization (ISO) 9001 and ISO 17025. However, not all laboratories are accredited [5]. There is no further information available on the website of the Ministry of Health [6].

[1] Institute for Public Health, Center for Medical Microbiology. [<https://www.ijzcg.me/me/centri/centar-za-medicinsku-mikrobiologiju>]. Accessed 07 January 2021.

[2] Institute for Public Health, Center for the Control and Prevention of Infectious Diseases.

[<https://www.ijzcg.me/me/centri/centar-za-kontrolu-i-prevenciju-zaraznih-bolesti>]. Accessed 07 January 2021.

[3] Accreditation Body of Montenegro. Responsibilities. [<http://www.atcg.co.me/cg/strana.php?id=2>]. Accessed 07 January 2021.

[4] Accreditation Body of Montenegro. List of Accredited Laboratories.

[<http://www.atcg.co.me/admindoc/organizacije/ZU%20Institut%20za%20javno%20zdravlje%20Crne%20Gore.zip>]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[6] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

2.1.2b

Is there a national laboratory that serves as a reference facility which is subject to external quality assurance review?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence to confirm that the Institute for Public Health of Montenegro, which serves as a reference laboratory, is subject to an external quality assurance review. The websites of the Institute for Public Health and Ministry of Health do not provide information about any external quality assurance review of the Institute [1, 2, 3]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, external quality assurance (EQA) is not conducted in the national reference laboratory, with the exception of antimicrobial residues (AMR), even though a few laboratories voluntarily participate in EQA schemes [4]. Further, there is no evidence of EQAs for the national reference laboratory in the Seventh External Quality Assessment Scheme for Salmonella typing issued

by ECDC and the External Quality Assurance System of the World Health Organization's (WHO) Global Foodborne Infections Network issued by WHO [5, 6].

[1] Institute for Public Health. Center for Medical Microbiology. [<https://www.ijzcg.me/me/centri/centar-za-medicinsku-mikrobiologiju>]. Accessed 07 January 2021.

[2] Institute for Public Health. Center for the Control and Prevention of Infectious Diseases. [<https://www.ijzcg.me/me/centri/centar-za-kontrolu-i-prevenciju-zaraznih-bolesti>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>] Accessed 07 January 2021

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[5] ECDC. 2016. "Seventh External Quality Assessment Scheme for Salmonella Typing". [<https://www.ssi.dk/-/media/arkiv/dk/sygdomme-beredskab-og-forskning/sygdomsovervaagning/ecdc-rapporter/eqa-7-salmonella.pdf?la=da>]. Accessed 07 January 2021.

[6] WHO. 2015. "External Quality Assurance System of the WHO Global Foodborne Infections Network". [<https://www.food.dtu.dk/english/-/media/Institutter/Foedevareinstituttet/Publikationer/Pub-2016/Rapport-The-External-Quality-Assurance-System-of-the-WHO-Global-Foodborne-Infections-Network-2015-pd.ashx?la=da&hash=746B23FCD994560410613E5A7ACE53E2FF4D685>]. Accessed 07 January 2021.

2.2 LABORATORY SUPPLY CHAINS

2.2.1 Specimen referral and transport system

2.2.1a

Is there a nationwide specimen transport system?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence of a nationwide specimen transport system in Montenegro.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, specimen transportation is conducted on an ad hoc basis by the Ministry of Health. The JEE states, "No specially defined specimen referral network related to human microbiology exists, nor is there a document that describes the network clearly" as well as that "there is no authorized courier service for referral of potentially communicable samples to laboratories outside Montenegro" [1]. Although there is evidence on the existence of private courier companies that transport pharmaceutical goods (including biological samples, clinical trials, shipments in dry ice, etc.) domestically and internationally, there is no evidence that this is a part of an established national specimen transport system [1,2].

However, the Law on Use of Biological Samples regulates the collection, use, storage, transportation, and destruction of biological samples of human origin, collected for medical purposes and scientific research, as well as the conditions that health institutions must fulfil to perform these tasks. The law does not elaborate on the transportation aspect, but it regulates that biological samples that are stored and transported in accordance with the purpose of their collection and use, medical doctrine and protocol, or special rules of profession and science, provided that their safety and confidentiality are ensured [3].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Cargo Team. [<http://cargo-team.com/>]. Accessed 07 January 2021.

[3] Parliament of Montenegro. 2010. "Law on Use of Biological Samples (Zakon o uzimanju i korišćenju bioloških uzoraka, Sl. CG 14/2010)." [<https://mzd.gov.me/biblioteka/zakoni/>]. Accessed 07 January 2021.

2.2.2 Laboratory cooperation and coordination

2.2.2a

Is there a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak?

Yes = 2 , Yes, but there is evidence of gaps in implementation = 1 , No = 0

Current Year Score: 0

Montenegro does not have a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak. The Law on Protection of Population from Infectious Diseases, Law on Accreditation, and Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro do not provide information about a plan to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak [1, 2, 3]. Further, the websites of the Ministries of Health, Agriculture, Security, and Institute for Public Health do not have a reference to a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak [4, 5, 6, 7].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4) ". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] Parliament of Montenegro. 2015. "Law on Accreditation (Zakon o akreditaciji, 'Sl. list CG', br. 54 od 10. avgusta 2009, 43/15) ".

[<http://www.mek.gov.me/ResourceManager/FileDownload.aspx?rid=260073&rType=2&file=Zakon%20o%20akreditaciji.pdf>]. Accessed 07 January 2021.

[3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021..

[4] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Agriculture, Forestry and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Ministry of Science. [<http://www.mna.gov.me/ministarstvo>]. Accessed 07 January 2021.

[7] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

2.3 REAL-TIME SURVEILLANCE AND REPORTING

2.3.1 Indicator and event-based surveillance and reporting systems

2.3.1a

Is there evidence that the country is conducting ongoing event-based surveillance and analysis for infectious disease?

Yes, there is evidence of ongoing event-based surveillance and evidence that the data is being analyzed on a daily basis = 2,
Yes, there is evidence of ongoing event-based surveillance, but no evidence that the data are being analyzed on a daily basis
= 1, No = 0

Current Year Score: 1

There is evidence that Montenegro conducts event-based surveillance and analysis for infectious diseases. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, Montenegro has a comprehensive surveillance system with various types of events-based surveillance and syndromic surveillance systems established. Event-based and syndromic surveillance systems take the form of twice-monthly epidemiological teleconferences in the country. The JEE also states that reports produced from events-based surveillance are made publicly available and shared with stakeholders on a regular basis. Further, the national reference laboratory, the Institute of Public Health, is finally responsible for verification of the surveillance data that is disseminated [1]. There is no further information regarding the events-based surveillance system available on the websites of the Ministries of Health and Agriculture and Institute for Public Health [2, 3, 4].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

2.3.1b

Is there publicly available evidence that the country reported a potential public health emergency of international concern (PHEIC) to the WHO within the last two years?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that Montenegro has reported a potential public health emergency of international concern (PHEIC) to the World Health Organization (WHO) within the last two years. The WHO's "Disease Outbreak News" webpages do not mention Montenegro as having reported a PHEIC in 2018, 2019, or 2020 [1, 2, 3]. Montenegro reported its first case of COVID-19 on March 17, 2020, after the WHO had already declared it a PHEIC on January 30, 2020 [5, 6].

[1] World Health Organization. "Disease Outbreak News. 2020." [<https://www.who.int/csr/don/archive/year/2020/en/>]. Accessed 26 May 2021.

[2] World Health Organization. "Disease Outbreak News. 2019." [<https://www.who.int/csr/don/archive/year/2019/en/>]. Accessed 26 May 2021.

[3] World Health Organization. "Disease Outbreak News. 2018." [<https://www.who.int/csr/don/archive/year/2018/en/>]. Accessed 26 May 2021.

[4] World Health Organization. [<https://www.who.int/>]. Accessed 26 May 2021.

[5] Garda World. March 18, 2020. "Montenegro: Country Confirms First Cases of COVID-19 March 17 /update 3". [<https://www.garda.com/crisis24/news-alerts/324271/montenegro-country-confirms-first-cases-of-covid-19-march-17-update-3>]. Accessed May 26, 2021.

[6] World Health Organisation (WHO). 27 April 2020. "Archived: WHO Timeline—COVID-19".

[<https://www.who.int/news/item/27-04-2020-who-timeline---covid-19>]. Accessed May 26, 2021.

2.3.2 Interoperable, interconnected, electronic real-time reporting systems

2.3.2a

Does the government operate an electronic reporting surveillance system at both the national and the sub-national level?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that the Government of Montenegro operates an electronic reporting surveillance system at both the national and sub-national levels.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, Montenegro has a "continuous and comprehensive electronic indicator-based surveillance system". The JEE mentions that the country's patient management system of medical practices has integrated the electronic case notification in it and that monitoring of infections is carried out in real-time. Accordingly, the JEE notes that high data processing enables regular reporting of surveillance data (weekly, monthly, and annually) [1]. Further, Montenegro operates the Integrated Health Information System (ZIS), which comprises a database of insured persons—patients; the payer's contributions; doctors; pharmacists database; dentist database; other medical staff; the database of health institutions; pharmaceuticals base according to ATC classification; diagnosis base, etc. The Information System of the Institute of Public Health, which contains data of all relevant register of diseases, is also integrated with ZIS. All data are available to authorized users [2]. In June 2018, the Ministry of Health adopted the "Strategy for Further Development of Integrated Health Information System and E-Health." According to this document, although ZIS is often identified as a monitoring and evaluation system, its role is much wider and more complex, including early warning systems, "management" of the patient and his health problems, overall health care, support for research purposes, health analysis, global reporting, and communication among different system users [3].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Enhancement of Cyber Educational System of Montenegro. Newsletter. [<http://ecesm.net/sites/default/files/Newsletter-no6.pdf>]. Accessed 07 January 2021.

[3] Ministry of Health. 2018. "Strategy for Further Development of Integrated Health Information System and E-Health (Strategija razvoja integralnog zdravstveno informacionog sistema i e-zdravlja (2018-2023))". [<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=336072&rType=2&file=Strategija%20razvoja%20Integralnog%20zdravstvenog%20informacionog%20sistema%20i%20e-zdravlja%202018-2023.pdf>]. Accessed 07 January 2021.

2.3.2b

Does the electronic reporting surveillance system collect ongoing or real-time laboratory data?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that the Government of Montenegro operates an electronic reporting surveillance system at both the national and sub-national levels that collect ongoing/real time laboratory data.

According to the Joint External Evaluation of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, Montenegro has a "continuous and comprehensive electronic indicator-based surveillance system". The JEE mentions that the country's patient management system of medical practices has integrated the electronic case notification

in it and that monitoring of infections is carried out in real-time. Accordingly, the JEE notes that high data processing allows for regular reporting of surveillance data (weekly, monthly, and annually) [1].

Montenegro operates the Integrated Health Information System (ZIS), which comprises a database of insured persons—patients; the payer's contributions; doctors; pharmacists database; dentist database; other medical staff; the database of health institutions; pharmaceuticals base according to ATC classification; diagnosis base, etc. The Information System of the Institute of Public Health, which contains data of all relevant register of diseases is also integrated with ZIS. All data are available to authorized users [2]. In June 2018, the Ministry of Health adopted the 'Strategy for Further Development of Integrated Health Information System and E-Health'. According to this document, although ZIS is often identified as a monitoring and evaluation system, its role is much wider and more complex, including early warning systems, "management" of the patient and his health problems, overall health care, support for research purposes, health analysis, global reporting and communication between different system users [3].

[1] World Health Organisation (WHO). March 17, 2021. "Joint external evaluation of IHR core capacities of Montenegro: mission report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Enhancement of Cyber Educational System of Montenegro. Newsletter. [<http://ecesm.net/sites/default/files/Newsletter-no6.pdf>]. Accessed 07 January 2021.

[3] Ministry of Health. 2018. "Strategy for Further Development of Integrated Health Information System and E-Health (Strategija razvoja integralnog zdravstveno informacionog sistema i e-zdravlja (2018-2023))".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=336072&rType=2&file=Strategija%20razvoja%20Integralnog%20zdravstvenog%20informacionog%20sistema%20i%20e-zdravlja%202018-2023.pdf>] Accessed 07 January 2021.

2.4 SURVEILLANCE DATA ACCESSIBILITY AND TRANSPARENCY

2.4.1 Coverage and use of electronic health records

2.4.1a

Are electronic health records commonly in use?

Electronic health records are commonly in use = 2, Electronic health records are not commonly in use, but there is evidence they are used = 1, No evidence electronic health records are in use = 0

Current Year Score: 0

There is no evidence that electronic health records are commonly used in Montenegro. Computerization of the health system by levels of health care was initiated in 2004. However, electronic health records are still not in use. According to the Strategy for Further Development of Integral Health Information System and E-Health, the electronic health record has thus far been developed only in principle, is not structured, and it is necessary continue to work on its structure and standardization. According to the strategy, further development of electronic health records will begin in the fourth quarter of 2018 [1]. In the previous period, the Health Insurance Fund, within the Integrated Health Information System (IISZ), has thus far developed and implemented eight electronic services intended for insured persons (eOrdering, ePrescription, eFounding, ePharmacy, eInsurance, eOrdering, eRealization of Rights, eCovid), which are available to insured persons or citizens on a mobile application and the eHealth Web portal. In accordance with the recognized needs of the insured and the health care system, from October 7, 2020 onward, a new electronic service called the electronic economic card (eEK) has been implemented and is in operation. [2] The website of the Ministry of Health does not provide additional information about the electronic health records [3]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "electronic case notification is integrated into the patient

management system of medical practices". However, the JEE does not provide any other information with regard to an e-health system for patient records [4].

[1] Ministry of Health. 2018. "Strategy for Further Development of Integral Health Information System and E-Health (Strategija razvoja integralnog zdravstveno informacionog sistema i e-zdravlja (2018-2023))".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=336072&rType=2&file=Strategija%20razvoja%20Integralnog%20zdravstvenog%20informacionog%20sistema%20i%20e-zdravlja%202018-2023.pdf>]. Accessed 07 January 2021.

[2] Fund for Health Insurance. Electronic Economic Card. [<https://fzocg.me/page.php?type=novost&id=313>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.4.1b

Does the national public health system have access to electronic health records of individuals in their country?

Yes = 1, No = 0

Current Year Score: 0

The national public health system in Montenegro does not have access to electronic health records of individuals, as there is no evidence that electronic health records are commonly in use in the country. Computerization of the health system by levels of health care was initiated in 2004. However, electronic health records are still not in use. According to the Strategy for Further Development of Integral Health Information System and E-Health, the electronic health record has thus far been developed only in principle, not structured, and it is necessary continue to work on its structure and standardization. According to the strategy, further development of electronic health records will begin in the fourth quarter of 2018 [1]. In the previous period, the Health Insurance Fund, within the Integrated Health Information System (IISZ), has thus far developed and implemented eight electronic services intended for insured persons (eOrdering, ePrescription, eFounding, ePharmacy, eInsurance, eOrdering, eRealization of Rights, eCovid), which are available to insured persons or citizens on a mobile application and the eHealth Web portal. In accordance with the recognized needs of the insured and the health care system, from October 7, 2020 a new electronic service called electronic economic card (eEK) has been implemented and is in operation [2]. The website of the Ministry of Health does not provide additional information about the electronic health records [3]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "electronic case notification is integrated into the patient management system of medical practices". However, the JEE does not provide any other information with regard to an e-health system for patient records [4].

[1] Ministry of Health. 2018. "Strategy for Further Development of Integral Health Information System and E-Health (Strategija razvoja integralnog zdravstveno informacionog sistema i e-zdravlja (2018-2023))".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=336072&rType=2&file=Strategija%20razvoja%20Integralnog%20zdravstvenog%20informacionog%20sistema%20i%20e-zdravlja%202018-2023.pdf>]. Accessed 07 January 2021.

[2] Fund for Health Insurance. Electronic Economic Card. [<https://fzocg.me/page.php?type=novost&id=313>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.

2.4.1c

Are there data standards to ensure data is comparable (e.g., ISO standards)?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence of data standards to ensure data is comparable (e.g., ISO standards). Computerization of the health system by levels of health care was initiated in 2004. However, electronic health records are still not in use. According to the Strategy for Further Development of Integral Health Information System and E-Health, the electronic health record has thus far been developed only in principle, is not structured, and it is necessary continue to work on its structure and standardization. According to the strategy, further development of electronic health records will begin in the fourth quarter of 2018 [1]. In the previous period, the Health Insurance Fund, within the Integrated Health Information System (IISZ), has thus far developed and implemented eight electronic services intended for insured persons (eOrdering, ePrescription, eFounding, ePharmacy, eInsurance, eOrdering, eRealization of Rights, eCovid), which are available to insured persons or citizens on the mobile application and the eHealth Web portal. In accordance with the recognized needs of the insured and the health care system, from October 7, 2020 a new electronic service called the electronic economic card (eEK) has been implemented and is in operation [2]. The website of the Ministry of Health does not provide additional information about the electronic health records [3]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "electronic case notification is integrated into the patient management system of medical practices". However, the JEE does not provide any other information in regards to an e-health system for patient records or in terms of standards for comparable EHR data [4].

[1] Ministry of Health. 2018. "Strategy for Further Development of Integral Health Information System and E-Health (Strategija razvoja integralnog zdravstveno informacionog sistema i e-zdravlja (2018-2023))".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=336072&rType=2&file=Strategija%20razvoja%20Integralnog%20zdravstvenog%20informacionog%20sistema%20i%20e-zdravlja%202018-2023.pdf>]. Accessed 07 January 2021.

[2] Fund for Health Insurance. Electronic Economic Card. [<https://fzocg.me/page.php?type=novost&id=313>]. Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.4.2 Data integration between human, animal, and environmental health sectors

2.4.2a

Is there evidence of established mechanisms at the relevant ministries responsible for animal, human, and wildlife surveillance to share data (e.g., through mosquito surveillance, brucellosis surveillance)?

Yes = 1, No = 0

Current Year Score: 1

In Montenegro, there is an established mechanism at the relevant ministries responsible for animal, human, and wildlife surveillance to share data (such as through mosquito surveillance, brucellosis surveillance, etc.).

Article 19 of the Law on the Protection of the Population from Infectious Diseases envisages that health institutions, veterinary organizations and administrative bodies competent for food safety, veterinary, and phytosanitary services are obliged to exchange information on the occurrence and movement of infectious diseases. Article 16 of the Law on the Protection of the Population from Infectious Diseases envisages that Institute for Public Health is obliged to monitor and study the movement of infectious diseases and informs the Ministry, other authorities and entities in the country (such as Directorate for Food Safety, Veterinary, and Phytosanitary) and abroad for the purpose of early warning and data exchange. Further, Article 9 of the Law envisages establishment of the Commission for Protection of the Population from Infectious Diseases whose main tasks are establishment of identification of measures concerning health protection, prevention, and detection of infectious diseases, treatment, and health care as well as the improvement and development of the health care service providers involved in the prevention, control, treatment of infectious diseases and the support of patients. Commission works on the basis of information received from the Institute for Public Health [1].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, there is a regular exchange of information and cooperation between public health and animal health sectors, with formal and informal systems for mutual reporting on zoonosis and zoonotic agents [2]. The Institute for Public Health (human health sector) and the Ministry of Agriculture and Rural Development, the Directorate for Food Safety, Veterinary, and Phytosanitary Affairs, and Specialist Veterinary Laboratory (animal health sector) share responsibility for zoonotic disease detection, surveillance, and reporting. Although informally, the relevant human health and animal health agencies collect data and submit regular reports on surveillance to each other [2].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4) ". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.4.3 Transparency of surveillance data

2.4.3a

Does the country make de-identified health surveillance data on infectious diseases publicly available via reports (or other format) on government websites (such as the Ministry of Health, Ministry of Agriculture, or similar)?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro makes de-identified health surveillance data on disease outbreaks publicly available via reports (or other format) on government websites. The Center for Control and Prevention of Infectious Diseases of the Institute for Public Health publishes monthly reports on infectious diseases. Some of the reported diseases are salmonellosis and varicella [1]. In addition, the institute also publishes statistical yearbooks that include, inter alia, data on the incidence of notified cases of diseases such as E. Coli. Gonorrhoea, Rubella, Tuberculosis, and Pneumonia [2]. Further, the Directorate for Food Safety, Veterinary, and Phytosanitary Affairs publishes monthly reports on animal infectious diseases. A few of the reported diseases are infectious rhinotracheitis of cattle, Leishmaniasis, etc. [3]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, surveillance of communicable diseases is conducted by trained epidemiologists. Weekly, monthly, and annual reports, epidemiological bulletins based on the mandatory notification, reports from event-based surveillance system, and additional reports according to epidemiological requirements are

produced and disseminated among stakeholders [4]. However, no such information is available on the websites of the Ministry of Health and Ministry of Agriculture [5, 6].

[1] Institute for Public Health. Monthly Reports on Infectious Diseases. [<https://www.ijzcg.me/me/izvjestaji/mjesečni-izvjestaji-o-kretanju-zaraznih-bolesti-u-crnoj-gori>]. Accessed 07 January 2021.

[2] Institute for Public Health. Statistical yearbooks. [<https://www.ijzcg.me/me/publikacije/statisticki-godisnjaci-o-zdravlju-stanovnistva-i-zdravstvenoj-zastiti-u-crnoj-gori>]. Accessed 07 January 2021.

[3] Directorate for Food Safety, Veterinary and Phytosanitary Affairs. Monthly Reports on Animal Infectious Diseases. [<http://www.ubh.gov.me/rubrike/mjesečni-izvjestaji>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[5] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

2.4.3b

Does the country make de-identified COVID-19 surveillance data (including details such as daily case count, mortality rate, etc) available via daily reports (or other formats) on government websites (such as the Ministry of Health, or similar)?

Yes = 1 , No = 0

Current Year Score: 1

Montenegro makes de-identified COVID-19 surveillance data (including details such as daily case count, mortality rate, etc.) available via daily reports (or other formats) on government websites (such as the Ministry of Health or similar). Such information are available on the official website of the Government of Montenegro and the National Coordination Body for Infectious Diseases of Montenegro. Information that is available is related to the number of infected cases, mortality rate, number of hospitalized persons, latest news, decisions of the government, introduced measures, etc. [1].

[1] Government of Montenegro. COVID-19. [<https://www.coronainfocg.me/>]. Accessed 07 January 2021.

2.4.4 Ethical considerations during surveillance

2.4.4a

Is there legislation and/or regulations that safeguard the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities?

Yes = 1 , No = 0

Current Year Score: 1

In Montenegro, there is a legal framework that safeguards the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities. According to Article 11 of the Law on Health Protection, secrecy of data is guaranteed to all patients. According to Article 139, health workers and health care professionals are obliged to keep all facts and information on the health conditions of the citizen a professional secret [1].

[1] Parliament of Montenegro. 2016. "Law on Health Protection (Zakon o zdravstvenoj zastiti, "Sl. list CG", br. 3/2016, 39/2016, 2/2017, 44/2018, 24/2019 - dr. zakoni i 82/2020). [<https://www.paragraf.me/propisi-crnegore/zakon-o->

zdravstvenoj-zastiti.html]. Accessed 07 January 2021.

2.4.4b

Is there legislation and/or regulations safeguarding the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, include mention of protections from cyber attacks (e.g., ransomware)?

Yes = 1, No = 0

Current Year Score: 0

In Montenegro, there is no legal framework that safeguards the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, including protection from cyber attacks. In Montenegro, secrecy of data and protection of patient's privacy is regulated by the Law on Health Protection. This law does not mention any protection from cyber attacks [1]. In addition, there is a law on the protection of personal data, but there are no references to protection from cyber attacks [2]. In addition, the websites of the Ministry of Health and Institute for Public Health do not provide information safeguarding the confidentiality of health information for individuals from cyber attacks [3, 4].

[1] Parliament of Montenegro. 2016. "Law on Health Protection (Zakon o zdravstvenoj zastiti, "Sl. list CG", br. 3/2016, 39/2016, 2/2017, 44/2018, 24/2019 - dr. zakoni i 82/2020). [<https://www.paragraf.me/propisi-crnegore/zakon-o-zdravstvenoj-zastiti.html>]. Accessed 07 January 2021.

[2] Parliament of Montenegro. 2008. "Law on Personal Data Protection (Zakon o zaštiti podataka o licnosti, Sl CG, 79/08, 70/09, 44/12). [<http://www.azlp.me/docs/zajednicka/zakoni/zakon-o-zastiti-podataka-o-licnosti.pdf>]. Accessed 07 January 2021

[3] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>] Accessed 07 January 2021

[4] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

2.4.5 International data sharing

2.4.5a

Has the government made a commitment via public statements, legislation and/or a cooperative agreement to share surveillance data during a public health emergency with other countries in the region?

Yes, commitments have been made to share data for more than one disease = 2, Yes, commitments have been made to share data only for one disease = 1, No = 0

Current Year Score: 0

There is insufficient evidence that the Government of Montenegro has made a commitment via public statements, legislation, and/or a cooperative agreement to share surveillance data during a public health emergency with other countries in the region for more than one disease.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, Montenegro's epidemiological surveillance capacity is strengthened as a result of close and routine "international collaboration and participation in regional and international networks such as the Network for Communicable Disease Control in Southern Europe and Mediterranean Countries (EpiSouth), EpiSouth Plus, and the Mediterranean Programme for Intervention Epidemiology Training (MediPIET)." The JEE notes that the European Surveillance System (TESSy) and the European Legionnaires' Disease Surveillance Network (ELDSNet) to be key regional partners with whom Montenegro

regularly collaborates and shares surveillance data. Accordingly, stakeholders of surveillance data receive "weekly, monthly, and annual reports, epidemiological bulletins based on the mandatory notification, reports from event-based surveillance system and additional reports according to epidemiological requirements" per the JEE [1]. It is unclear if this happens during public health emergencies.

There is no further information on international collaboration for health surveillance data available on the website of the Ministry of Health [2].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>] Accessed 07 January 2021.

2.5 CASE-BASED INVESTIGATION

2.5.1 Case investigation and contact tracing

2.5.1a

Is there a national system in place to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of a public health emergency?

Yes, there is evidence that the national government supports sub-national systems to prepare for future public health emergencies = 2, Yes, there is evidence that the national government supports sub-national systems, but only in response to active public health emergencies = 1, No = 0

Current Year Score: 0

In Montenegro, there is no evidence of a national system in place to provide support at the sub-national level (e.g., training, metrics standardization and/or financial resources) to conduct contact tracing in the event of an active or future public health emergency.

One of the special measures to protect the population from infectious diseases is defined in Articles 22 and 24 of the Law on Protection of Population from Infectious Diseases and involves early detection of sources, reservoirs, and routes of transmission. However, there are no specific provisions in the Law regarding how to provide support at the sub-national level (e.g., training, metrics standardization, and/or financial resources) to expand contact tracing in the event of a public health emergency [1]. The websites of the Ministry of Health and Institute for Public Health do not have further information about contact tracing in the event of a public health emergency [2, 3].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, there is a gap in the tracing of suspected cases of zoonotic disease, for analysis and evaluation as well as for documentation and reporting by the human and animal health sectors. The JEE, under Emergency Preparedness, also recommends that training sessions and exercises must be organized to implement national plans [4].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<https://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>] Accessed 07 January 2021.

[2] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>] Accessed 07 January 2021

[3] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.5.1b

Does the country provide wraparound services to enable infected people and their contacts to self-isolate or quarantine as recommended, particularly economic support (paycheck, job security) and medical attention?

Yes, both economic support and medical attention are provided = 2, Yes, but only economic support or medical attention is provided = 1, No = 0

Current Year Score: 2

Montenegro provides wraparound services to enable infected people and their contacts to self-isolate or quarantine, as recommended, particularly economic support (paycheck, job security) and medical attention. One of the special measures to protect the population from infectious diseases are defined in Article 33 of the Law on Protection of Population from Infectious Diseases is health surveillance and quarantine [1]. According to Article 13 of the Law on Obligatory Health Insurance, employees have the right to medical attention and compensation of earnings during temporary incapacity for work. In addition, according to Article 37, compensation of earning belongs to the insured if they are temporarily prevented from working due to illness or injury, placed under health supervision or quarantined, etc. [2]. Further, the official website dedicated to COVID-19 also provides detailed information regarding labor obligations and rights during the COVID-19 pandemic (e.g., home-based work, compensation during absence from work, etc.) [3]. All these measures are applicable on the entire territory of Montenegro. The websites of the Ministry of Health, Ministry of Economy, and Institute for Public Health do not have information about wraparound services [4, 5, 6]. Moreover, the Joint External Evaluation (JEE) of IHR core capacities does not have information about wraparound services [7].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<https://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>] Accessed 07 January 2021.

[2] Parliament of Montenegro. 2016. "Law on Obligatory Health Insurance (Zakon o obaveznom zdravstvenom osiguranju, "Sl. list CG", br. 6/2016, 2/2017, 22/2017, 13/2018 i 67/201)". [<https://www.paragraf.me/propisi-crnegore/zakon-o-zdravstvenom-osiguranju.html>]. Accessed 07 January 2021.

[3] Government of Montenegro. COVID-19. [<https://www.coronainfocg.me/>]. Accessed 07 January 2021.

[4] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Economy. [<https://mek.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

[7] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.5.1c

Does the country make de-identified data on contact tracing efforts for COVID-19 (including the percentage of new cases from identified contacts) available via daily reports (or other format) on government websites (such as the Ministry of Health, or similar)?

Yes = 1, No = 0

Current Year Score: 0

Montenegro does not make de-identified data on contact tracing efforts for COVID-19 (including the percentage of new cases from identified contacts) available via daily reports (or other format) on government websites. The official website dedicated to COVID-19 provides the latest information related to COVID-19 in Montenegro. These reports include information such as the number of tested people, number of infected people, and number of recoveries, etc. However, these sources do not make de-identified data from contact tracing available [1]. There is no further evidence on the Ministry of Health [2].

[1] Government of Montenegro. COVID-19. [<https://www.coronainfocg.me/>]. Accessed 07 January 2021.

[2] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>] Accessed 07 January 2021.

2.5.2 Point of entry management

2.5.2a

Is there a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of a public health emergency?

Yes, plan(s)/agreement(s) are in place to prepare for future public health emergencies = 2, Yes, but plan(s)/agreement(s) are in place only in response to active public health emergencies = 1, No = 0

Current Year Score: 0

There is no evidence that Montenegro has a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases among international travelers and trace and quarantine their contacts in the event of an active or future public health emergency. The Law on the Protection of the Population from Infectious Diseases, Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018–2023 and Action Plan for Improvement of System for Supervision and Response on Infectious Diseases 2017–2022 do not regulate these issues [1, 2, 3]. Further, the websites of the Ministry of Health and Ministry of Interior do not have further information about cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of a public health emergency [4, 5]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, the Ministry of Health is responsible for developing "management plan for crisis and emergency situations such as outbreaks, extreme climate conditions and other accidents and disasters" while the "Directorate for Emergencies within the Ministry of Interior is responsible for the country's overall emergency response and for the coordination of responses by other government departments in an emergency." However, there is no further information on public health and border control agency collaboration during public health emergencies given in the JEE [6].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<https://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>] Accessed 07 January 2021.

[2] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamickim planom aktivnosti za sprovedjenje strategije za period 2018-2023. godine)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[3] Ministry of Health. 2017. "Action Plan for Improvement of System for Supervision and Response on Infectious Diseases 2017-2022, with the Report on implemented activities for period 2015-2017 (Akcioni plan za unapre?enje sistema za nadzor i odgovor na zarazne bolesti 2017-2022, sa Izvještajem o realizovanim aktivnostima za period 2015-2017. godine)".

[<http://www.gov.me/ResourceManager/FileDownload.aspx?rId=294809&rType=2>]. Accessed 07 January 2021.

[4] Ministry of Health. [<http://www.mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.6 EPIDEMIOLOGY WORKFORCE

2.6.1 Applied epidemiology training program, such as the field epidemiology training program, for public health professionals and veterinarians (e.g., Field Epidemiology Training Program [FETP] and Field Epidemiology Training Program for Veterinarians [FETPV])

2.6.1a

Does the country meet one of the following criteria?

- Applied epidemiology training program (such as FETP) is available in country
- Resources are provided by the government to send citizens to another country to participate in applied epidemiology training programs (such as FETP)

Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

Current Year Score: 1

There is evidence that an applied epidemiology training program (such as the Field Epidemiology Training Programme (FETP)) is available in Montenegro, and resources are provided by the government to send citizens to another country to participate in applied epidemiology training programs.

The "Action Plan for Improvement of System for Supervision and Response on Infectious Diseases, 2017–2022, with the Report on implemented activities for period 2015–2017" defines different planned and implemented capacity building measures for epidemiologists, microbiologists, and other specialists. This document reports that Montenegrin representatives participated in the Mediterranean Programme for Intervention Epidemiology Training (MediPIET). This programme was organized abroad and the Montenegrin Government funded the participants [1]. The specific goals of MediPIET are to train national trainers and supervisors; training a regional cadre of field epidemiologists competent in intervention epidemiology; disseminating experience, knowledge, and skills; fostering country commitment/ownership and regional networking; and establishing the basis of a long-term regional training programme [2].

Further, according to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021 entitled "A three-year academic specialization programme in epidemiology is in place, with a clear structure and legal and financial support". In addition, FETP capacity building is in place through participation in MediPIET [3].

The websites of the Ministry of Health and Institute for Public Health do not have information about applied epidemiology training programs being available in Montenegro [4, 5].

[1] Ministry of Health. 2017. "Action Plan for Improvement of System for Supervision and Response on Infectious Diseases, 2017–2022, with the Report on implemented activities for period 2015–2017 (Akcioni plan za unapredjenje sistema za nadzor i odgovor na zarazne bolesti 2017-2022, sa Izvještajem o realizovanim aktivnostima za period 2015-2017. godine)". [<http://www.gov.me/ResourceManager/FileDownload.aspx?rId=294809&rType=2>]. Accessed 07 January 2021.

[2] Mediterranean Programme for Intervention Epidemiology Training as an approach to addressing international health risks in the Mediterranean Region. 2018. CORDS 2018 All Networks Conference. [<https://www.cordsnetwork.org/wp-content/uploads/2018/03/Mediterranean-Programme-for-Intervention-Epidemiology-Training-as-an-approach-to-addressing-international-health-risks-in-the-Mediterranean-region-2.pdf>]. Accessed 07 January 2021.

[3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

2.6.1b

Are the available field epidemiology training programs explicitly inclusive of animal health professionals or is there a specific animal health field epidemiology training program offered (such as FETPV)?

Yes = 1, No = 0

Current Year Score: 1

There is evidence that Montenegro has participated in an applied epidemiology training program involving veterinarians.

The Action Plan for Improvement of System for Supervision and Response on Infectious Diseases, 2017–2022, with the Report on Implemented Activities for the period 2015–2017 defines different planned and implemented capacity building measures for epidemiologists, microbiologists, veterinary and medical doctors, and other specialists. Some of the implemented epidemiology capacity building programs, where Montenegrin representatives participated, is the Mediterranean intervention program epidemiology (MediPIET). This program was organized abroad and the Montenegrin Government fund the participants [1]. The specific goals of MediPIET are training national trainers and supervisors; training a regional cadre of field epidemiologists competent in intervention epidemiology; disseminating experience, knowledge, and skills; fostering country commitment/ownership and regional networking; and establishing the basis of a long-term regional training program [2].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "Intensive in-service training in animal health is in place, supported by international organizations "such as WHO, European Centre for Disease Prevention and Control (ECDC), OIE, and Better Training for Safer Food (BTSF), or partner countries including Serbia, Croatia, Bosnia and Herzegovina, Greece, and Germany" in both short and long format courses [3].

[1] Ministry of Health. 2017. "Action Plan for Improvement of System for Supervision and Response on Infectious Diseases 2017–2022, with the Report on Implemented Activities for the Period 2015–2017 (Akcioni plan za unapredjenje sistema za nadzor i odgovor na zarazne bolesti 2017-2022, sa Izvještajem o realizovanim aktivnostima za period 2015-2017. godine)". [<http://www.gov.me/ResourceManager/FileDownload.aspx?rid=294809&rType=2>]. Accessed 07 January 2021.

[2] Mediterranean Programme for Intervention Epidemiology Training as an Approach to Addressing International Health Risks in the Mediterranean Region. 2018. CORDS 2018 All Networks Conference. [<https://www.cordsnetwork.org/wp-content/uploads/2018/03/Mediterranean-Programme-for-Intervention-Epidemiology-Training-as-an-approach-to-addressing-international-health-risks-in-the-Mediterranean-region-2.pdf>]. Accessed 07 January 2021.

[3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

2.6.2 Epidemiology workforce capacity

2.6.2a

Is there public evidence that the country has at least 1 trained field epidemiologist per 200,000 people?

Yes = 1, No = 0

Current Year Score: 0

2020

Completed JEE assessments; Economist Impact analyst qualitative assessment based on official national sources, which vary by country

Category 3: Rapid response to and mitigation of the spread of an epidemic

3.1 EMERGENCY PREPAREDNESS AND RESPONSE PLANNING

3.1.1 National public health emergency preparedness and response plan

3.1.1a

Does the country have an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential?

Evidence that there is a plan in place, and the plan is publicly available = 2, Evidence that the plan is in place, but the plan is not publicly available OR, Disease-specific plans are in place, but there is no evidence of an overarching plan = 1, No evidence that such a plan or plans are in place = 0

Current Year Score: 2

There is evidence that Montenegro has an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential.

The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, mentions that Montenegro has a "Law on the protection of population against communicable diseases (Official Gazette of Montenegro, No. 012/18)," which serves as its overarching national public health emergency response plan and is made publicly available on the VERTIC BWC database [1, 2]. The 2018 Law lists 75 different types of communicable diseases that it covers, including cholera, bacterial infections, tuberculosis, anthrax, brucellosis, tetanus, gonorrhoea, Brill disease, Q fever, viral encephalitis caused by tick, yellow fever, Ebola, chickenpox, malaria, flu (influenza), and pneumonia, among others [3]. It covers measures for prevention and control of specific diseases, implementation, and the funding of such programs. Further, the law includes general measures such as sanitary guidelines, awareness and education of diseases, and disinfection of populated areas as well as special measures, such as immunoprophylaxis and haemioophylaxis; medical checkups of certain population categories with counseling, health care supervision and quarantine; laboratory testing in order to identify infective disease agents and epidemic agents; early detection and reporting of infective diseases and epidemiological supervision; epidemiological testing; health care education of the infected members of their families and other persons who are at a risk to contract a disease; and disinfection, disinfestation, and deratization as per epidemiological indications [3].

The JEE also states that a "rulebook on notifying about communicable diseases, hospital-acquired infections, states and death cases caused by these diseases (Official Gazette of Montenegro, No. 020/2019)", a "rulebook on the list of communicable diseases with epidemiological supervision and against which measures are implemented aimed at preventing and suppressing communicable diseases and defining the cases of communicable diseases (Official Gazette of Montenegro, No. 020/2019)", and a draft of "response plan in case of outbreak of a communicable disease in air traffic posing a threat to public health" are in place in the country [1].

In March 2020, the Government of Montenegro also adopted the COVID-19 Preparedness and Response Plan [4].

The websites of the Ministry of Health and Ministry of Interior do not have additional information about a national public health emergency response plan in place which addresses planning for multiple communicable diseases with pandemic potential [5, 6].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] The Verification Research, Training, and Information Centre (VERTIC). "VERTIC BWC Legislation Database". [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed May 27, 2021.

[3] The Verification Research, Training, and Information Centre (VERTIC). "Law on the Protection of Population Against Communicable Diseases". [http://www.vertic.org/media/National%20Legislation/Montenegro/ME_Law_Prevention_Population_Infectious_Diseases.pdf]. Accessed May 27, 2021.

[4] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[5] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

3.1.1b

If an overarching plan is in place, has it been updated in the last 3 years?

Yes = 1 , No /no plan in place= 0

Current Year Score: 0

There is no evidence that Montenegro's overarching national public health emergency response plan, which addresses planning for multiple communicable diseases with epidemic or pandemic potential, has been updated in the last three years. The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, mentions that Montenegro has a "Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 012/18)," which serves as its overarching national public health emergency response plan and is made publicly available on the VERTIC BWC database [1, 2]. This Law itself was put in place three years ago in 2018 [1, 2, 3].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] The Verification Research, Training, and Information Centre (VERTIC). "VERTIC BWC Legislation Database".

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed May 27, 2021.

[3] The Verification Research, Training, and Information Centre (VERTIC). "Law on the Protection of Population against Communicable Diseases".

[http://www.vertic.org/media/National%20Legislation/Montenegro/ME_Law_Prevention_Population_Infectious_Diseases.pdf]. Accessed May 27, 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

3.1.1c

If an overarching plan is in place, does it include considerations for pediatric and/or other vulnerable populations?

Yes = 1 , No /no plan in place= 0

Current Year Score: 0

There is insufficient evidence that Montenegro has an overarching national public health emergency response plan, which includes considerations for pediatric and/or other vulnerable populations.

The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, mentions that Montenegro has a "Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 012/18)," which serves as its overarching national public health emergency response plan and is made publicly available on the VERTIC BWC database [1, 2]. The Law makes "immunoprophylaxis and haemoprophyllaxis compulsory under Articles 16, 17, 18, and 19, requires medical check ups for certain persons, including pregnant women, blood, and organ donors, those treated with haemodialysis, people employed in the medical sector, those employed in sectors specifically catering to children and senior citizens, those employed in providing medical treatment and sanitary services, those employed in cosmetic and dermatological service sectors; "persons entering the Republic from the countries reporting cholera, plague, viral haemorrhagic fevers (except for haemorrhagic fever with renal syndrome) or malaria, and according to the epidemiological indications the persons who may import other infective diseases determined by a competent government authority"; and "persons secreting the infective agents of abdominal typhoid, paratyphoid, other salmonellas, shigelloses, yersiniosa and campylobacterialis." [3] However, there is no specific mention of vulnerable or pediatric populations in the Law [3].

The websites of the Ministry of Health and Ministry of Interior do not provide additional information about considerations for pediatric and other vulnerable populations [4, 5].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] The Verification Research, Training, and Information Centre (VERTIC). "VERTIC BWC Legislation Database". [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed May 27, 2021.

[3] The Verification Research, Training, and Information Centre (VERTIC). "Law on the Protection of Population against Communicable Diseases".

[http://www.vertic.org/media/National%20Legislation/Montenegro/ME_Law_Prevention_Population_Infectious_Diseases.pdf]. Accessed May 27, 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

3.1.1d

Does the country have a publicly available plan in place specifically for pandemic influenza preparedness that has been updated since 2009?

Yes = 1 , No = 0

Current Year Score: 0

2020

WHO Strategic Partnership for IHR and Health Security (SPH)

3.1.2 Private sector involvement in response planning

3.1.2a

Does the country have a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro has a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response.

The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, mentions that Montenegro has a "Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 012/18)," which serves as its overarching national public health emergency response plan and is made publicly available on the VERTIC BWC database [1, 2]. However, this Law makes no mention of engaging private sector in emergency preparedness and response [3]. Further, the National Action Plan for the protection from chemical, biological, radiological, and nuclear threats and risks for the period 2016–2020 and the Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the strategy for the period 2018–2023 do not have any references related to cooperation with the private sector in case of outbreak emergency situations [4, 5].

Further, the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro does not have information about a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response [6]. It only mentions that state resources are pooled with the staff resources of local government bodies, private companies, non-governmental organizations (NGOs), and individuals when coordinating for emergency risk communication [6].

The COVID-19 Preparedness and Response Plan has identified importance of the private sector to be included in case identification and surveillance. However, it does not elaborate a specific mechanism(s) for their engagement [7].

In addition, the websites of the Ministry of Health and Ministry of Interior do not have information about specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response [8, 9].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228->

eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.

[2] The Verification Research, Training and Information Centre (VERTIC). "VERTIC BWC Legislation Database".

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed May 27, 2021.

[3] The Verification Research, Training, and Information Centre (VERTIC). "Law on the protection of Population against Communicable Diseases".

[http://www.vertic.org/media/National%20Legislation/Montenegro/ME_Law_Prevention_Population_Infectious_Diseases.pdf]. Accessed May 27, 2021.

[4] Government of Montenegro. "National Action Plan for Protection for Chemical, Biological, Radiological and Nuclear Threats and Risks for Period 2016–2020 (Nacionalni akcioni plan za zaštitu od hemijskih, bioloških, radioloških i nuklearnih prijetnji i rizika (HBRN) za period 2016-2020)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=237958&rType=2&file=5_157_12_05_2016.pdf]. Accessed 07 January 2021.

[5] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamičkim planom aktivnosti za sprovođenje strategije za period 2018-2023. godine)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[6] World Health Organisation (WHO). 2019. "Joint External Evaluation of IHR Core Capacities of Montenegro".

[<https://extranet.who.int/sph/sites/default/files/jeeta/Montenegro%20-%20JEE%20Report.pdf>]. Accessed 14 April 2021.

[7] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[8] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>] Accessed 07 January 2021

[9] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

3.1.3 Non-pharmaceutical interventions planning

3.1.3a

Does the country have a policy, plan and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic?

Yes, a policy, plan and/or guidelines are in place for more than one disease = 2, Yes, but the policy, plan and/or guidelines exist only for one disease = 1, No = 0

Current Year Score: 2

Montenegro has a policy, plan, and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic for more than one disease.

The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, mentions that Montenegro has a "Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 012/18)" that serves as its overarching national public health emergency response plan and is made publicly available on the Verification Research, Training, and Information Centre (VERTIC) BWC database [1, 2]. The Law lists 75 different types of communicable diseases that it covers, including tuberculosis, anthrax, gonorrhoea, Brill disease, Q fever, ebola, chickenpox, flu (influenza), and pneumonia, among others [3]. It covers measures for prevention and control of specific diseases as well as the implementation and funding of such programs. The law includes several NPIs, such as sanitary guidelines, awareness and education of diseases, and disinfection of populated areas, as well as special measures,

health care education of the infected members of their families and other persons who are at a risk of contracting a disease. Under Article 34, the Law also mentions travel arrangement measures; population migration restrictions; closures of populated venues, events, and places; and trade restrictions. Article 39 also sets penalties worth five to ten times the minimum wage in case of violations of enforced restrictions [3].

Montenegro also has a COVID-19 Preparedness and Response Plan that outlines NPIs, but this plan is design specifically for COVID-19 and it cannot be used for other diseases [4]. Further, the websites of the Ministry of Health, Ministry of Interior, and Institute for Public Health do not have additional information regarding a policy, plan, and/or guidelines in place to implement NPIs during an epidemic or pandemic [5, 6, 7].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] The Verification Research, Training, and Information Centre (VERTIC). "VERTIC BWC Legislation Database". [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/m/>]. Accessed May 27, 2021.

[3] The Verification Research, Training, and Information Centre (VERTIC). "Law on the Protection of Population against Communicable Diseases".

[http://www.vertic.org/media/National%20Legislation/Montenegro/ME_Law_Prevention_Population_Infectious_Diseases.pdf]. Accessed May 27, 2021.

[4] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>]. Accessed 07 January 2021

[6] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[7] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

3.2 EXERCISING RESPONSE PLANS

3.2.1 Activating response plans

3.2.1a

Does the country meet one of the following criteria?

- Is there evidence that the country has activated their national emergency response plan for an infectious disease outbreak in the past year?

- Is there evidence that the country has completed a national-level biological threat-focused exercise (either with WHO or separately) in the past year?

Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

Current Year Score: 1

Montenegro has activated its national emergency response plan for an infectious disease outbreak in the past year, but there is no evidence that the country has completed a national-level biological threat-focused exercise (either with the World Health Organization (WHO) or separately) in the past year.

Further, there is no publically available information on the websites of the Ministry of Health, Ministry of Interior, and

Institute for Public Health regarding the activation of the national emergency response plan or a national-level biological threat-focused exercise [1, 2, 3]. However, in March 2020, the first COVID-19 cases were registered in Montenegro when the COVID-19 Preparedness and Response Plan was adopted and activated [4]. The WHO simulation exercise and strategic partnership portal do not have evidence that the country has completed a national-level biological threat-focused exercise (either with the WHO or separately) in the past year [5, 6]. There is also no evidence that Montenegro activated its overarching national public health emergency response plan in place, which addresses planning for multiple communicable diseases with epidemic or pandemic potential entitled "Law on the Protection of Population against Communicable Diseases (Official Gazette of Montenegro, No. 012/18)" [7].

[1] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>]. Accessed 07 January 2021

[2] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021.

[4] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[5] World Health Organisation (WHO). Simulation exercise activities—Montenegro. [<https://extranet.who.int/sph/simulation-exercise?region=All&country=313>]. Accessed 07 January 2021.

[6] World Health Organization (WHO). "Strategic Partnerships Portal". [<https://extranet.who.int/sph/country/montenegro>]. Accessed 07 January 2021.

[7] Government of Montenegro. "News". [<https://www.gov.me/en/>]. Accessed May 27, 2021.

3.2.1b

Is there evidence that the country in the past year has identified a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) and developed a plan to improve response capabilities?

Yes, the country has developed and published a plan to improve response capacity = 2 , Yes, the country has developed a plan to improve response capacity, but has not published the plan = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro in the past year has identified a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) and developed a plan to improve response capabilities. According to information available on the World Health Organization's (WHO) Strategic Partnership Portal and WHO After Action Review, Montenegro did not identify a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) or develop a plan to improve response capabilities [1, 2]. Further, a WHO assessment of health system preparedness has not been performed for Montenegro [3]. There is no publicly available information on this on the websites of the Ministry of Health, Institute for Public Health, and Directorate for Emergency Situations [4, 5, 6].

[1] World Health Organization (WHO). "Strategic Partnerships Portal". [<https://extranet.who.int/sph/country/montenegro>]. Accessed 07 January 2021.

[2] World Health Organization (WHO). After Action Review. [<https://extranet.who.int/sph/after-action-review>]. Accessed 07 January 2021.

[3] World Health Organization (WHO). 2011. "Assessment of Health-system Crisis Preparedness". [<http://www.euro.who.int/en/search?q=Assessment+of+health-system+crisis+preparedness+-+Montenegro>]. Accessed 07 January 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021

[5] Institute for Public Health. [<http://www.ijzcg.me/>]. Accessed 07 January 2021

[6] Ministry of Interior. Directorate for Emergency Situations. [<http://www.mup.gov.me/rubrike/vanredne-situacije/nadleznosti>]. Accessed 07 January 2021.

3.2.2 Private sector engagement in exercises

3.2.2a

Is there evidence that the country in the past year has undergone a national-level biological threat-focused exercise that has included private sector representatives?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro has undergone a national-level biological threat-focused exercise in the past year that has included private sector representatives. According to information available on the World Health Organization's (WHO) Strategic Partnership Portal and WHO Simulation Exercise, Montenegro has not undergone a national-level biological threat-focused exercise that has included private sector representatives [1, 2]. There is no publically available information on the websites of the Ministry of Health, Ministry of Agriculture, Institute for Public Health, and Directorate for Emergency Situations [3, 4, 5, 6].

[1] World Health Organization (WHO). "Strategic Partnerships Portal". [<https://extranet.who.int/sph/country/montenegro>]. Accessed 07 January 2021.

[2] World Health Organization (WHO). "Simulation Exercise". [<https://extranet.who.int/sph/simulation-exercise>] Accessed 07 January 2021.

[3] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>] Accessed 07 January 2021.

[4] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<http://www.ijzcg.me/>]. Accessed 07 January 2021.

[6] Ministry of Interior. Directorate for Emergency Situations. [<http://www.mup.gov.me/rubrike/vanredne-situacije/nadleznosti>]. Accessed 07 January 2021.

3.3 EMERGENCY RESPONSE OPERATION

3.3.1 Emergency response operation

3.3.1a

Does the country have in place an Emergency Operations Center (EOC)?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that Montenegro has an Emergency Operations Center (EOC) in place.

The Directorate for Emergency Situations of the Ministry of Interior is the EOC of Montenegro. According to Article 29 of the Law on Protection and Rescue, the Ministry of Interior is responsible for overall coordination and commanding of all operational bodies involved in the system of rescue and protection in emergency situations. Article 4 elaborates that disasters include various types of disasters and specifically includes infectious disease epidemics as one of the types of natural disasters that the law covers [1]. The main responsibilities of the Directorate are analysis and monitoring of the situation in the field of protection and rescue; giving instructions for management in protection and rescue and proposing

measures for protection and rescue participants; collecting data on threats, causes, and consequences of emergencies; providing assistance in removing the consequences of emergencies, etc. Further, the Operational and Communication Center 112 is part of this Directorate [2]. According to Article 22 of the Law on Rescue and Protection, the Ministry of Interior coordinates the actions during the duration of an emergency event, including health emergencies [1].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, the Directorate for Emergencies within the Ministry of Interior, through its 112 EOC "handles continuous collection and submission of data related to an emergency in affected areas". It also states that since 2015, the country has had a fully operational 112 EOC in place. However, the JEE also notes that "there is no medical operation centre available 24/7 to deal with threats" [3].

[1] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zastiti%20i%20spasavanju.pdf>] Accessed 07 January 2021.

[2] Ministry of Interior. Directorate for Emergency Situations. [<http://www.mup.gov.me/rubrike/vanredne-situacije/nadleznosti>]. Accessed 07 January 2021.

[3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

3.3.1b

Is the Emergency Operations Center (EOC) required to conduct a drill for a public health emergency scenario at least once per year or is there evidence that they conduct a drill at least once per year?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that the Emergency Operations Center (EOC) is required to conduct a drill for a public health emergency scenario at least once per year or that they conduct a drill at least once per year.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "the Directorate for Emergencies, which is based in the Ministry of Interior, is responsible for risk management, protection and rescue in emergencies, and manages the consequences of these emergencies" and that it handles continuous data collection on emergency response through its 112 EOCs. In addition, the JEE mentions that there is no medical operations center that runs 24/7. The JEE also mentions that a number of exercises have been conducted by the EOC since 2013 but does not mention a requirement or the frequency of said exercises; it only states that "regular exercises to test response at the national and local levels should be strengthened" [1].

Further, according to the "Law on Protection and Rescue," members of the protection service units are obliged to be professionally trained, but there is no evidence of a requirement for annual drills in the text [2]. The Ministry of Interior has also adopted "Annual Training Programs" and in its annual reports on the annual trainings and drills organized in relation to the system of protection and rescue. A few of the organized trainings by the Ministry of Interior comprise "Work with dangerous goods" and "System of rescue and protection", but do not suggest an annual drill or requirement of such an annual drill. [3]. There is no further information available on the websites of the Ministry of Interior and Ministry of Health [4, 5].

- [1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.
- [2] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)". [<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zastiti%20i%20spasavanju.pdf>]. Accessed 07 January 2021.
- [3] Ministry of Interior. 2019. "Annual Report on the system of protection and rescue in 2018 (Izveštaj o stanju sistema zaštite i spašavanja u 2018. godini)". [https://www.gov.me/ResourceManager/FileDownload.aspx?rid=353422&rType=2&file=21_114_21_03_2019.pdf]. Accessed 07 January 2021.
- [4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021
- [5] Ministry of Interior. Directorate for Emergency Situations. [<http://www.mup.gov.me/rubrike/vanredne-situacije/nadleznosti>]. Accessed 07 January 2021.

3.3.1c

Is there public evidence to show that the Emergency Operations Center (EOC) has conducted within the last year a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient public evidence to show that the Emergency Operations Center (EOC) has, within the last year, conducted a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "the Directorate for Emergencies, which is based in the Ministry of Interior, is responsible for risk management, protection and rescue in emergencies, and manages the consequences of these emergencies" and that it handles continuous data collection on emergency response through its 112 EOC. In addition, the JEE mentions that there is no medical operations center that runs 24/7. The JEE also mentions that a number of exercises have been conducted by the EOC since 2013, but it does not mention a coordinated emergency response within the 2019–2020 period or whether one was activated within 120 minutes of identification of a public health emergency scenario [1].

Further, there is no information regarding this in the Annual Report on the system of protection and rescue in 2018 of the Ministry of Interior or the websites of the World Health Organization (WHO), the Ministry of Health, and the Institute for Public Health [2, 3, 4, 5].

- [1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.
- [2] Ministry of Interior. 2019. "Annual Report on the System of Protection and Rescue in 2018 (Izveštaj o stanju sistema zaštite i spašavanja u 2018. godini)". [https://www.gov.me/ResourceManager/FileDownload.aspx?rid=353422&rType=2&file=21_114_21_03_2019.pdf]. Accessed 07 January 2021.
- [3] World Health Organization. 2017. "Calendar of Activities". [<https://extranet.who.int/sph/country/montenegro>]. Accessed

07 January 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021

[6] Institute for Public Health. Center for Science. [<http://www.ijzcg.me/centri/centar-za-nauku/>]. Accessed 07 January 2021.

3.4 LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

3.4.1 Public health and security authorities are linked for rapid response during a biological event

3.4.1a

Does the country meet one of the following criteria?

- Is there public evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack)?

- Are there publicly available standard operating procedures, guidelines, memorandums of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e., bioterrorism attack)?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

In Montenegro, there is no evidence that public health and national security authorities have conducted an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack) or there is no publicly available standard operating procedures, guidelines, memorandums of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e., bioterrorism attack).

According to the Report on the System of Protection and Rescue in 2018, representatives of Montenegro participated in a NATO EADRCC International field exercise on managing the consequences of emergency situations called "Serbia 2018" that was organised in Serbia in October 2018. The exercise scenario referred to practicing action and cooperation in case of earthquakes, floods, and chemical, biological, and radiation accidents. The exercises were preceded by two conferences held in Belgrade. However, this was not a response exercise for a deliberate biological event [1, 2].

Further, there is no information of such an exercise on the websites of the Ministry of Interior and Ministry of Health [3, 4]. Information on standard operating procedures, guidelines, MOUs, or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e., bioterrorism attack) are not publicly available on the websites of the Ministry of Health, Ministry of Interior, and Institute for Public Health [2, 3, 4].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, at the national level, the army of Montenegro has the capacity to manage emergency biological situations. A number of exercises have been held since 2013 to plan for emergencies and accidents. These include a biological accident simulation; a regional South Eastern Europe Simulation (SEESIM) exercise; a NATO exercise on flooding and a chemical accident; regional and national chemical, biological, radiological, and nuclear (CBRN) scenarios; earthquake response; and a table-top exercise on communicable diseases in flight. However, there is no information on standard operating procedures, guidelines, MOUs or other agreements between the public health and security authorities or exercises to respond to a potential deliberate biological event (i.e., bioterrorism attack). The JEE also notes that the Ministry of Interior's Directorate for Emergencies initiated the "Disaster Risk Assessment for Montenegro," which would provide "detailed threat analysis of CBRN (chemical/biological/radiation/nuclear) accidents, as well as of earthquakes, extreme weather events, floods, fires, avalanches, landslides, epidemics, epiphytotics, epizootics, industrial accidents, traffic accidents, accidents at sea, civil aviation accidents, climate change, critical

infrastructure protection, and terrorism" but goes on to state that only radiological assessments have been conducted in the last five years preceding 2019. In fact, the JEE mentions "Project 44," a notable regional CBRN exercise, in which Montenegro participated in 2015, and there is no evidence of a more recent exercise [5].

[1] Ministry of Interior. 2019. "Annual Report on the System of Protection and Rescue in 2018 (Izveštaj o stanju sistema zaštite i spašavanja u 2018. godini).

[https://www.gov.me/ResourceManager/FileDownload.aspx?rid=353422&rType=2&file=21_114_21_03_2019.pdf]. Accessed 07 January 2021.

[2] Ministry of Interior. Directorate for Emergency Situations. Guidance.

[http://www.mup.gov.me/biblioteka/direktorat_VS/uputstva]. Accessed 07 January 2021

[3] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka?query=biolo%u0161k&sortDirection=desc>].

Accessed 07 January 2021.

[4] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

3.5 RISK COMMUNICATIONS

3.5.1 Public communication

3.5.1b

Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) outline how messages will reach populations and sectors with different communications needs (eg different languages, location within the country, media reach)?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that the risk communication plan (or other legislation, regulation, or strategy document used to guide national public health response) outline how messages will reach populations and sectors with different communications needs (e.g., different languages, location within the country, media reach) as there is insufficient evidence of a risk communication plan in the country.

Articles 21–25a of the Law on Protection and Rescue regulates informing and alerting in case of emergency situations. The Law envisages that the main communication instrument is unique Communication System 112, while the main alerting system is unique alert signs of the notification system [1]. The Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for the implementation of the strategy for the period 2018–2023 also refers to unique communication system 112 and unique alert signs as the main instruments for communication and alerting. The strategy also refers to the Ordinance on Unique Alert Signs and Alerting Methods, but this document is not publicly available [2].

The COVID-19 Preparedness and Response Plan has provisions related to risk communication and communication with the community [3]. However, these documents do not outline how messages would reach populations with different communication needs (e.g., different languages, location within country, etc.).

Further, the websites of the Ministry of Interior and Ministry of Health do not provide additional information about instruments used to communicate with the population with different communication needs [4, 5]. There is no evidence of

risk communication measures for reach populations and sectors with different communications needs in the "Law on Protection and Rescue" and the "Law on the Protection of the Population from Infectious Diseases" [6, 7].

[1] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zastiti%20i%20spasavanju.pdf>]. Accessed 07 January 2021.

[2] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018-2023 (Strategija za smanjenje rizika od katastrofa sa dinamicnim planom aktivnosti za sprovedenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[3] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[4] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<http://www.mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zastiti%20i%20spasavanju.pdf>]. Accessed 07 January 2021.

[7] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4) ". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021

3.5.1 Risk communication planning

3.5.1a

Does the country have in place, either in the national public health emergency response plan or in other legislation, regulation, or strategy documents, a section detailing a risk communication plan that is specifically intended for use during a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro has in place, either in the national public health emergency response plan or in other legislation, regulation, or strategy documents, a section detailing a risk communication plan that is specifically intended for use during a public health emergency.

Section 3.1.3 of the Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the strategy for the period 2018–2023 refers to public health emergency situations. However, in this section, there are no references related to communication in case of public health emergencies [1].

"The Law on Protection and Rescue" and the "Law on the Protection of the Population from Infectious Diseases" do not have a section detailing a risk communication plan that is specifically intended for use during a public health emergency [2, 3].

"The National Action Plan for Protection for Chemical, Biological, Radiological, and Nuclear Threats and Risks for the Period 2016–2020" highlights the importance of communication among relevant authorities; however, it does not contain any plan

how these authorities must communicate [4].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, despite informal and formal communication and coordination within the health care system, there is no all hazards legislation for risk communication. The JEE also notes that, nonetheless, there are annual internal reviews of and exercises for protection and rescue system communication. As such, the JEE specifies that Montenegro has "expanded its communication strategy, with the support of the UK Government, to include crisis communications" [5].

The COVID-19 Preparedness and Response Plan has provisions related to risk communication and communication with the community [5]. However, no further information is available on the website of the Ministry of Health [6].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamičkim planom aktivnosti za sprovođenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[2] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zaštiti%20i%20spasavanju.pdf>]. Accessed 07 January 2021.

[3] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[4] Government of Montenegro. "National Action Plan for Protection for Chemical, Biological, Radiological and Nuclear Threats and Risks for the Period 2016–2020 (Nacionalni akcioni plan za zaštitu od hemijskih, bioloških, radioloških i nuklearnih prijetnji i rizika (HBRN) za period 2016-2020)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=237958&rType=2&file=5_157_12_05_2016.pdf]. Accessed 07 January 2021.

[5] World Health Organization (WHO). 2019. "Joint External Evaluation of IHR Core Capacities of Montenegro".

[<https://extranet.who.int/sph/sites/default/files/jeeta/Montenegro%20-%20JEE%20Report.pdf>]. Accessed 14 April 2021.

[6] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[7] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka?query=biolo%u0161k&sortDirection=desc>] Accessed 07 January 2021.

3.5.1c

Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) designates a specific position within the government to serve as the primary spokesperson to the public during a public health emergency, as there is insufficient evidence of a risk communication plan in the country.

The Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the strategy for the period 2018–2023, Law on Protection and Rescue, Law on the Protection of the Population from Infectious Diseases, National Action Plan for Protection for Chemical, Biological, Radiological, and Nuclear Threats and Risks for the period 2016–2020, and COVID-19 Preparedness and Response Plan do not designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency [1, 2, 3, 4, 5]. In addition, such information is not available on the website of the Ministry of Health and Institute for Public Health [6, 7]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, no formal designation for risk communication exists in the country although the Ministry of Interior is responsible for risk communications in the country at large [8].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinami?kim planom aktivnosti za sprovo?enje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[2] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zaštiti%20i%20spasavanju.pdf>]. Accessed 07 January 2021.

[3] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021

[4] Government of Montenegro. "National Action Plan for Protection for Chemical, Biological, Radiological and Nuclear Threats and Risks for Period 2016–2020 (Nacionalni akcioni plan za zaštitu od hemijskih, bioloških, radioloških i nuklearnih prijetnji i rizika (HBRN) za period 2016-2020)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=237958&rType=2&file=5_157_12_05_2016.pdf]. Accessed 07 January 2021.

[5] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[6] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka?query=biolo%u0161k&sortDirection=desc>]. Accessed 07 January 2021.

[7] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

[8] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

3.5.2 Public communication

3.5.2a

In the past year, is there evidence that the public health system has actively shared messages via online media platforms (e.g. social media, website) to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation?

Public health system regularly shares information on health concerns = 2, Public health system shares information only during active emergencies, but does not regularly utilize online media platforms = 1, Public health system does not regularly utilize online media platforms, either during emergencies or otherwise = 0

Current Year Score: 1

There is evidence that the public health system has actively shared messages via online media platforms (e.g., social media, website) to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation, but do not regularly utilize online media platforms. The Government of Montenegro has a specific website dedicated to COVID-19 [1]. On the websites of the institutes for public health, there is evidence that the public health system has actively shared messages to inform the public about ongoing public health concerns, like influenza. These reports include data such as the number of laboratory-confirmed cases of influenza virus, their geographical distribution, intensity of activity, and trend of incidence as well as the incidence of acute respiratory infections, etc. but there is no information regarding wellness and general health concerns [2]. The Institute for Public Health of Montenegro does use social media (e.g., Facebook) [3].

[1] Government of Montenegro. COVID-19. [<https://www.coronainfocg.me/>]. Accessed 07 January 2021.

[2] Institute for Public Health. "Influenza: Weekly Epidemiological Surveillance Reports." [<https://www.ijzcg.me/me/izvjestaji/nedjeljni-izvjestaji-o-epidemioloskom-nadzoru-nad-gripom-u-sezoni-2019-2020>]. Accessed 07 January 2021.

[3] Institute for Public Health. Facebook page. [<https://www.facebook.com/ijzcg/>]. Accessed 07 January 2021.

3.5.2b

Is there evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years?

No = 1, Yes = 0

Current Year Score: 1

There is no evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years. Moreover, there is no information about shared misinformation or disinformation on infectious diseases in the past two years on the websites of the President of Montenegro and Ministry of Health and media outlets [1, 2, 3, 4].

[1] President of Montenegro. [<http://www.predsjednik.me/>]. Accessed 07 January 2021.

[2] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Glas Amerike. 2020. "Markovic: We won the battle, Montenegro is the first Corona-free country in Europe". [<https://www.glasamerike.net/a/markovi%C4%87-crna-gora-je-prva-korona-fri-zemlja-u-evropi/5434811.html>]. Accessed 07 January 2021.

[4] RTCG. 2020. "Prohibition of Public Gatherings if a Virus Occurs". [<http://www.rtcg.me/vijesti/drustvo/271986/zabrana-javnih-okupljanja-ako-se-pojavi-virus.html>]. Accessed 07 January 2021.

3.6 ACCESS TO COMMUNICATIONS INFRASTRUCTURE

3.6.1 Internet users

3.6.1a

Percentage of households with Internet

Input number

Current Year Score: 73.48

2019

International Telecommunication Union (ITU)

3.6.2 Mobile subscribers

3.6.2a

Mobile-cellular telephone subscriptions per 100 inhabitants

Input number

Current Year Score: 183.28

2019

International Telecommunication Union (ITU)

3.6.3 Female access to a mobile phone

3.6.3a

Percentage point gap between males and females whose home has access to a mobile phone

Input number

Current Year Score: 0

2019

Gallup; Economist Impact calculation

3.6.4 Female access to the Internet

3.6.4a

Percentage point gap between males and females whose home has access to the Internet

Input number

Current Year Score: 1.0

2019

Gallup; Economist Impact calculation

3.7 TRADE AND TRAVEL RESTRICTIONS

3.7.1 Trade restrictions

3.7.1a

In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 1

There is no evidence that Montenegro, in the past year, has issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g., medicines, oxygen, medical supplies, personal protective equipment (PPE)) due to an infectious disease outbreak. Moreover, there is no information about such restrictions on the websites of the Ministry of Economic Development, Ministry of Health, and the Institute for Public Health [1, 2, 3].

[1] Ministry of Economic Development. [<https://mek.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

3.7.1b

In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g. food, textiles, etc) due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 1

There is no evidence that Montenegro, in the past year, has issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g., food, textiles, etc) due to an infectious disease outbreak. Moreover, there is no information on such restrictions on the websites of the Ministry of Economic Development, Ministry of Health and Institute for Public Health there are no information [1, 2, 3].

[1] Ministry of Economic Development. [<https://mek.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

3.7.2 Travel restrictions

3.7.2a

In the past year, has the country implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 0

In the past year, Montenegro has implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak. In March 2020, Montenegro reported its first case of COVID-19 and the pandemic is still ongoing [1]. In March 2020, the Government of Montenegro introduced a ban on travelers entering Montenegro due to the COVID-19 outbreak [2]. The government of Montenegro also initiated restrictions on border crossings, with entry points with Vuča (with Serbia) and Metaljka (with BiH) being closed during the pandemic [3].

[1] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[2] Radio slobodna Evropa. 2020. "Montenegro: Application of Several Measures against the Spread of Coronavirus Extended

until April 30". [<https://www.slobodnaevropa.org/a/30557742.html>]. Accessed 07 January 2021.

[3] OECD. 31 January 2021. "The COVID-19 Crisis in Montenegro". [<https://www.oecd.org/south-east-europe/COVID-19-Crisis-in-Montenegro.pdf>]. Accessed 27 May 2021.

Category 4: Sufficient and robust health sector to treat the sick and protect health workers

4.1 HEALTH CAPACITY IN CLINICS, HOSPITALS, AND COMMUNITY CARE CENTERS

4.1.1 Available human resources for the broader healthcare system

4.1.1a

Doctors per 100,000 people

Input number

Current Year Score: 275.57

2018

WHO; national sources

4.1.1b

Nurses and midwives per 100,000 people

Input number

Current Year Score: 522.94

2018

WHO; national sources

4.1.1c

Does the country have a health workforce strategy in place (which has been updated in the past five years) to identify fields where there is an insufficient workforce and strategies to address these shortcomings?

Yes = 1, No = 0

Current Year Score: 1

There is evidence that Montenegro has a public workforce strategy in place (which has been updated in the past five years) to identify fields where there is an insufficient public health workforce and strategies to address these shortcomings.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, Montenegro has a workforce development plan for health care workers in the human health sector as well as an employment needs plan for veterinary professionals in the animal health sector for the 2013–2022 time period. The JEE also states that the country has a "legal framework and a clear organizational structure for setting up epidemiological field teams for the surveillance, prevention and control of communicable infections". Further, the JEE notes the government's commitment to enforcing a human resource plan for personnel recruitment as well as continuing education. As such, there are several trainings in place for surveillance and detection capacity building. Nevertheless, the JEE recommends that Montenegro develop a multisectoral workforce strategy, which is routinely reviewed and updated [1].

In Section 2.3 of the National Strategy for Employment and Development of Human Resources 2016–2020 (Trends on the Labour Market) identifies fields where there is an insufficient workforce. However, this section does not identify fields in the public health workforce where there are shortages [2]. The strategies to address shortcomings are elaborated in the abovementioned document as well as in the Annual Programme of Work issued by the National Employment Agency. However, this document also does not identify fields specifically in the public health workforce where there are shortages [3].

Another document that provides analysis of shortcomings is the annual document entitled "Analysis of supply, demand, and employment on the labour market in Montenegro," which analyzes the labour market at the level of individual degrees, occupational groups, or professions at macro, regional, and micro levels. Based on the analysis, at the micro level, the document identifies an insufficient public health workforce in certain municipalities (e.g., nurse of general health care and medical technician of general health care), but it does not provide strategies to address these shortcomings [4].

The websites of the Ministries of Health, Economic Development and Education do not have further information about insufficient public health workforce and strategies to address these shortcomings [5, 6, 7].

[1] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[2] Ministry of Labor and Social Affairs. 2015. "National Strategy for Employment and Development of Human Resources 2016-2020 (Nacionalna strategija zapošljavanja i razvoja ljudskih resursa 2016-2020)". [<http://www.gov.me/ResourceManager/FileDownload.aspx?rId=224091&rType=2>]. Accessed 07 January 2021.

[3] Employment Agency of Montenegro. 2019. "Programme of Work for 2019 (Program rada za 2019. godinu)". [<http://www.zzzcg.me/wp-content/uploads/2019/01/Program-rada-za-2019.-godinu.docx>]. Accessed 07 January 2021.

[4] Employment Agency of Montenegro. 2017. "Analysis of Supply, Demand and Employment on the Labor Market in Montenegro in 2016 (Analiza ponude, tražnje i zapošljavanja na tržištu rada u Crnoj Gori u 2016. godini)". [<http://www.zzzcg.me/wp-content/uploads/2017/05/Analiza-ponude-traznje-i-zaposljavanja-na-trzistu-rada-u-Crnoj-Gori-u-2016-godini.pdf>]. Accessed 07 January 2021.

[5] Ministry of Health. [<http://www.mzdravlja.gov.me/ministarstvo>]. Accessed 10 September 2018.

[6] Ministry of Economic Development. [<https://mek.gov.me/ministarstvo>]. Accessed 10 September 2018.

[7] Ministry of Education, Science, Culture, and Sports. [<https://mps.gov.me/ministarstvo>]. Accessed 10 September 2018.

4.1.2 Facilities capacity

4.1.2a

Hospital beds per 100,000 people

Input number

Current Year Score: 386

2017

WHO/World Bank; national sources

4.1.2b

Does the country have the capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit and/or patient isolation room/unit located within the country?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro has the capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit and/or patient isolation facility located within the country. According to Article 43 of the Law on Protection of Population from Infectious Diseases, persons found to be ill or suspected of being infected with infectious diseases are obliged to be isolated and treated in the health care facilities that have conditions for insurance for isolation and treatment of patients with infectious diseases [1]. However, there is no information on the websites of the Ministry of Health and Clinical Center of Montenegro, Clinic for Infectious Diseases regarding the capacity to isolate patients with highly communicable diseases [2, 3]. In addition, there is information about the future reconstruction of the Clinical Center in Montenegro. The European Union (EU) and Government of Montenegro will invest 17 million euro for reconstruction of different clinics, including Clinic for Infectious Diseases [4]. According to documentation related to the reconstruction (i.e., "Preliminary Design of the Reconstruction of the Clinical Center"), construction of facilities for strict isolation with 46 beds has been planned [5]. However, it is not evident whether these facilities would be capable of isolating from highly contagious pathogens. Further, the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro does not have information about the Montenegrin capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit and/or patient isolation facility located within the country [6].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4) ". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Clinical Center of Montenegro. Clinic for Infectious Diseases. [<http://www.kccg.me/klinike-i-centri/klinike/klinika-za-infektivne-bolesti/>]. Accessed 07 January 2021

[4] AA. 2020. "Montenegro: The Government, in Co-operation with the EU, is Investing 17 Million Euro in the Reconstruction of Clinics". [<https://www.aa.com.tr/ba/balkan/crna-gora-vlada-u-saradnji-sa-eu-ula%C5%BEE-17-miliona-eura-za-rekonstrukciju-klinika/1870859>]. Accessed 07 January 2021.

[5] ING-INVEST doo. "Preliminary Design".

[http://195.66.166.132/idejno_rjesenje/2018/IR/109_08_03_2018_IR_KCCG_Klinika_za_kozne_i_infektivne_bolesti_Podgorica.pdf]. Accessed 07 January 2021.

[6] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

4.1.2c

Does the country meet one of the following criteria?

- Is there evidence that the country has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years?

- Is there evidence that the country has developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro has demonstrated the capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years and has not developed, updated, or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years. There is no information on the websites of the Ministry of Health and Clinical Center of Montenegro, Clinic for Infectious Diseases, regarding the capacity to expand isolation capacity in response to an infectious disease outbreak and developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak [1, 2]. In addition, there is information regarding the future reconstruction of the Clinical Center in Montenegro. The European Union (EU) and the Government of Montenegro will invest 17 million euro for reconstruction of different clinics, including Clinic for Infectious Diseases [3]. According to documentation related to the reconstruction (i.e., "Preliminary Design of the Reconstruction of the Clinical Centre"), the construction of facilities for strict isolation with 46 beds has been planned [4]. However, it is not evident whether these facilities would be capable of isolating from highly contagious pathogens and this capacity is not currently in place. The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, does not have information about the capacity to expand isolation capacity in response to an infectious disease outbreak or developed, updated, or tested a plan to expand isolation capacity in response to an infectious disease outbreak [5].

[1] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[2] Clinical Center of Montenegro. Clinic for Infectious Diseases. [<http://www.kccg.me/klinike-i-centri/klinike/klinika-za-infektivne-bolesti/>]. Accessed 07 January 2021

[3] AA. 2020. "Montenegro: The Government, in Co-operation with the EU, is Investing 17 Million Euro in the Reconstruction of Clinics". [<https://www.aa.com.tr/ba/balkan/crna-gora-vlada-u-saradnji-sa-eu-ula%C5%BEE-17-miliona-eura-za-rekosntrukciju-klinika/1870859>]. Accessed 07 January 2021.

[4] ING-INVEST doo. "Preliminary Design".

[http://195.66.166.132/idejno_rjesenje/2018/IR/109_08_03_2018_IR_KCCG_Klinika_za_kozne_i_infektivne_bolesti_Podgorica.pdf]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

4.2 SUPPLY CHAIN FOR HEALTH SYSTEM AND HEALTHCARE WORKERS

4.2.1 Routine health care and laboratory system supply

4.2.1a

Is there a national procurement protocol in place which can be utilized by the Ministries of Health and Agriculture for the acquisition of laboratory supplies (e.g. equipment, reagents and media) and medical supplies (e.g. equipment, PPE) for routine needs?

Yes for both laboratory and medical supply needs = 2, Yes, but only for one = 1, No = 0

Current Year Score: 2

In Montenegro, there is a national procurement protocol in place which can be utilized by the Ministries of Health and Agriculture for the acquisition of laboratory supplies (e.g., equipment, reagents and media) and medical supplies (e.g., equipment and personal protective equipment (PPE)) for routine needs. The public procurement system, including the acquisition of laboratory and medical supplies, is regulated by the Law on Public Procurement [1]. The websites of the Montenegro Institute for Public Health, as an institution subordinated to the Ministry of Health and Directorate for Food Safety, Veterinary, and Fitosanitary Affairs, as an institution subordinated to the Ministry of Agriculture, contain information regarding the procurement of different laboratory and medical supplies. Procurement processes are implemented in line with the Law on Public Procurement [2, 3]. All tenders are published on the procurement portal managed by the Directorate for Public Procurement [4].

[1] Parliament of Montenegro. 2017. "Law on Public Procurement (Zakon o javnim nabavkama, Sl. CG 042/11, 057/14, 028/15 i 042/17)". [<http://www.ujn.gov.me/wp-content/uploads/2018/02/Zakon-o-javnim-nabavkama-pre%C4%8Di%C5%A1%C4%87em-tekst-2017-godina-1.pdf>]. Accessed 07 January 2021.

[2] Institute for Public Health. "Public Procurement". [<https://www.ijzcg.me/me/javne-nabavke-instituta-za-javnog-zdravlje-crne-gorepreview-modetrue>]. Accessed 07 January 2021.

[3] Directorate for Food Safety, Veterinary and Fitosanitary Affairs. "Public Procurement". [https://ubh.gov.me/biblioteka/javne_nabavke]. Accessed 07 January 2021.

[4] Directorate for Public Procurement. Public Procurement Portal. [<http://portal.ujn.gov.me/delta2015/login.jsp>]. Accessed 07 January 2021.

4.2.2 Stockpiling for emergencies

4.2.2a

Does the country have a stockpile of medical supplies (e.g. MCMs, medicines, vaccines, medical equipment, PPE) for national use during a public health emergency?

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

Current Year Score: 0

There is no evidence that Montenegro has a stockpile of medical supplies (e.g., MCMs, medicines, vaccines, medical equipment, or personal protective equipment (PPE)) for national use during a public health emergency. According to Article 46 the Law on the Protection of the Population from Infectious Diseases, health institutions that conduct epidemiological surveillance and treatments of infectious diseases are obliged to provide a reserve of medicines in the case of a widespread disease. Epidemiological surveillance is carried out over infectious diseases, health-related infections, and antimicrobial

resistance in accordance with the definition of the case, the recommendations of the European Center for Prevention and Control of Disease, and the World Health Organization (WHO) (Article 4). The list of infectious diseases over which epidemiological surveillance is performed and against which measures to prevent the eradication of infectious diseases are applied is determined by the Ministry of Health on the proposal of the Institute for Public Health (Article 3) [1]. In addition, based on Article 18 of the Ordinance on Criteria for Placing and Removal of Medicines from the list of medicines, the manufacturer or the authorized distributor, in case of impossibility of continuous supply of the medicinal product, is obliged to inform the Ministry of Health not later than the moment when the quantity of the medicinal product is available in the stock for another three months of continuous supply [2]. The list of medicines also includes MCMs like vaccines [3]. However, in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro and on the websites of the Ministry of Health, Institute of Public Health and Fund for Health Insurance, there is no information regarding a stockpile of medical supplies (e.g., MCMs, medicines, vaccines, medical equipment, and personal protective equipment (PPE)) for national use during a public health emergency [4, 5, 6, 7]. COVID-19 Preparedness and Response Plan highlights the importance of the medical supplies (e.g., equipment and PPE) for national use during COVID-19 pandemic, but based on this document it cannot be confirmed that Montenegro has a stockpile of medical supplies (e.g., equipment and PPE) for national use during a public health emergency [8].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] Ministry of Health. 2016. "Ordinance on Criteria for Placing and Removal of Medicines from the List of Medicines (Uredba o kriterijumima za stavljanje, odnosno skidanje lijekova sa liste lijekova)".

[<https://fzocg.me/Administracija/Documents/1570176691Uredba%20o%20kriterijumima%20za%20stavlanje%20odnosno%20skidanje%20lijevakova%20sa%20liste%20lijevakova.pdf>] Accessed 07 January 2021.

[3] Fund for Health Insurance. 2018. "Decision on Determining the List of Drugs (Odluka o utrdjivanju Liste lijekova)".

[http://fzocg.me/documents/Lista_lijevakova/Odluka_o_utrvivanju_Liste_lijevakova_-_NOVEMBAR_2018.pdf]. Accessed 07 January 2021.

[4] Ministry of Health. "Documents". [<http://www.mzdravlja.gov.me/biblioteka?query=biolo%u0161k&sortDirection=desc>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

[6] Fund for Health Insurance. [<https://fzocg.me/>]. Accessed 07 January 2021.

[7] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[8] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

4.2.2b

Does the country have a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

Current Year Score: 0

There is no evidence that Montenegro has a stockpile of laboratory supplies (e.g., reagents, media) for national use during a public health emergency. The Law on the Protection of the Population from Infectious Diseases does not elaborate details related to laboratory supplies [1]. The COVID-19 Preparedness and Response Plan highlights the importance of the laboratory

supplies for national use during COVID-19 pandemic, but based on this document it cannot be confirmed that Montenegro has a stockpile of laboratory supplies (e.g., reagents and media) for national use during a public health emergency [2]. The Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro and the websites of the Ministry of Health and Institute for Public Health do not have additional information about laboratory supplies (e.g., reagents and media) for national use during a public health emergency [3, 4, 5].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>].

[3] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[4] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

4.2.2c

Is there evidence that the country conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Montenegro conducts or requires an annual review of the national stockpile to ensure that the supply is sufficient for a public health emergency.

According to Article 46 of the 2018, the "Law on the Protection of the Population from Infectious Diseases," health institutions that carry out epidemiological surveillance and treatments of infectious diseases are obliged to provide a reserve of medicines in the case of a widespread disease. However, there is no further information regarding maintaining and reviewing national stockpiles in this Law [1].

In addition, based on Article 18 of the Ordinance on Criteria for Placing and Removal of Medicines from the List of Medicines, the manufacturer or the authorized distributor, in the case of impossibility of continuous supply of the medicinal product, is obliged to inform the Ministry of Health not later than the moment when the quantity of the medicinal product is available in the stock for another three months of continuous supply [2]. The list of medicines also includes MCMs, like vaccines [3]. However, these acts do not require the government to conduct an annual review of the national stockpile to ensure that the supply is sufficient for a public health emergency.

There is no further information regarding an annual review of national stockpiles in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro and on the websites of the Ministry of Health, Institute of Public Health, and Fund for Health Insurance [4, 5, 6, 7].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

- [2] Ministry of Health. 2016. "Ordinance on Criteria for Placing and Removal of Medicines from the List of Medicines (Uredba o kriterijumima za stavljanje, odnosno skidanje lijekova sa liste lijekova)".
[<https://fzocg.me/Administracija/Documents/1570176691Uredba%20o%20kriterijumima%20za%20stavljavanje%20odnosno%20skidanje%20lijeikova%20sa%20liste%20lijeikova.pdf>]. Accessed 07 January 2021.
- [3] Fund for Health Insurance. 2018. "Decision on Determining the List of Drugs (Odluka o utvrđivanju Liste lijekova)".
[http://fzocg.me/documents/Lista_lijeikova/Odluka_o_utvrivanju_Liste_lijeikova_-_NOVEMBAR_2018.pdf]. Accessed 07 January 2021.
- [4] Ministry of Health. Documents. [<http://www.mzdravlja.gov.me/biblioteka?query=biolo%u0161k&sortDirection=desc>]
Accessed 07 January 2021.
- [5] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>] Accessed 07 January 2021.
- [6] Fund for Health Insurance. [<https://fzocg.me/>]. Accessed 07 January 2021.
- [7] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

4.2.3 Manufacturing and procurement for emergencies

4.2.3a

Does the country meet one of the following criteria?

- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?
- Is there evidence of a plan/mechanism to procure medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is no evidence that Montenegro has a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e. g., MCMs, medicines, vaccines, equipment, and personal protective equipment (PPE)) for national use during a public health emergency. However, there is evidence that Montenegro has a plan/mechanism to procure medical supplies (e. g., MCMs, medicines, vaccines, equipment, and PPE) for national use during a public health emergency.

The "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018–2023" and the "Law on the Protection of the Population from Infectious Diseases" do not regulate these issues [1, 2]. The "COVID-19 Preparedness and Response Plan" has a section regulating procurement of different supplies, but it is specifically designed for COVID-19 [3]. Responding to a request via the European Union (EU) Civil Protection Mechanism, during the COVID-19 outbreak, Slovenia offered surgical masks and different kinds of disinfectants to Montenegro [4]. Further, there is no information about a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e. g., MCMs, medicines, vaccines, equipment, and PPE) for national use during a public health emergency or evidence of a plan/mechanism to procure medical supplies (e. g., MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency given in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro and on the websites of the Ministry of Health, Ministry of Economic Development, and Institute for Public Health [5, 6, 7, 8].

Montenegro has been part of the EU Joint Procurement Agreement for Medical Countermeasures, which ensures that member states have access to medical countermeasures from abroad if necessary when a serious cross-border threat to health is registered. The agreement aims to "secure more equitable access to specific medical countermeasures and improved security of supply" as well as balancing prices for EU member states. It is also designed to ensure acquisition of

vaccines, antivirals, and medical countermeasures for serious cross-border threats to health [9].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamičkim planom aktivnosti za sprovođenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[2] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[3] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[4] European Commission. "Coronavirus: EU Channels Assistance to Montenegro and Kosovo".

[https://ec.europa.eu/echo/news/coronavirus-eu-channels-assistance-montenegro-and-kosovo_en]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27-31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[6] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[7] Ministry of Economic Development. [<https://mek.gov.me/ministarstvo>]. Accessed 07 January 2021.

[8] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

[9] European Commission. "Joint Procurement Of Medical Countermeasures".

[https://ec.europa.eu/health/preparedness_response/joint_procurement_en]. Accessed 3 September 2020.

4.2.3b

Does the country meet one of the following criteria?

- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

- Is there evidence of a plan/mechanism to procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

There is no evidence of a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e. g., reagents, media) for national use during a public health emergency or any evidence of a plan/mechanism to procure laboratory supplies (e. g., reagents, media) for national use during a public health emergency. The "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018–2023" and the "Law on the Protection of the Population from Infectious Diseases" do not regulate these issues [1, 2]. Further, the "COVID-19 Preparedness and Response Plan" has a section regulating procurement of different supplies, but it is specifically designed for COVID-19 [3]. There is no information about a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e. g., reagents, media) for national use during a public health emergency or a plan/mechanism to procure laboratory supplies (e. g., reagents, media) for national use during a public health emergency given in the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro and on the websites of the Ministry of Health, Ministry of Economic Development, and Institute for Public Health [4, 5, 6, 7].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamikim planom aktivnosti za sprovedjenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf].

Accessed 07 January 2021.

[2] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>] Accessed 07 January 2021.

[3] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[5] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Ministry of Economic Development. [<https://mek.gov.me/ministarstvo>]. Accessed 07 January 2021.

[7] Institute for Public Health. [<https://www.ijzcg.me/me/o-nama>]. Accessed 07 January 2021.

4.3 MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

4.3.1 System for dispensing medical countermeasures (MCM) during a public health emergency

4.3.1a

Does the country have a plan, program, or guidelines in place for dispensing medical countermeasures (MCM) for national use during a public health emergency (i.e., antibiotics, vaccines, therapeutics and diagnostics)?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that Montenegro has a plan, program, or guidelines in place for dispensing medical countermeasures for national use during a public health emergency (i.e., antibiotics, vaccines, therapeutics, and diagnostics).

According to Article 28 of the Law on the Protection of the Population from Infectious Diseases, health institutions that conduct epidemiological surveillance and treatments of infectious diseases are obliged to provide a reserve of medicines in the case of a widespread disease. However, this document does not refer specifically to dispensing medical countermeasures for national use during a public health emergency [1].

In addition, the websites of the Ministry of Health, Ministry of Defense, Institute for Public Health, and Agency for Medicines and Medical Devices do not contain information about a plan, program, or guidelines in place for dispensing medical countermeasures for national use during a public health emergency [2, 3, 4, 5].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, during an emergency, the prime minister can set up and lead a multisectoral coordination team, which would hold responsibility for the procurement and distribution of medical countermeasures. However, the JEE does not mention dispensing of MCMs [6].

- [1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4) ". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.
- [2] Ministry of Health. [<https://mzd.gov.me/ministarstvo/>]. Accessed 07 January 2021
- [3] Ministry of Defense. [<http://www.mod.gov.me/ministarstvo/>]. Accessed 07 January 2021.
- [4] Institute for Public Health. [<https://www.ijzcg.me/>]. Accessed 07 January 2021
- [5] Agency for Medicines and Medical Devices. [<https://medicalcg.me/>]. Accessed 07 January 2021.
- [6] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

4.3.2 System for receiving foreign health personnel during a public health emergency

4.3.2a

Is there a public plan in place to receive health personnel from other countries to respond to a public health emergency?

Yes = 1 , No = 0

Current Year Score: 0

In Montenegro, there is no evidence of a public plan to receive health personnel from other countries to respond to a public health emergency.

According to Article 37 of the "Law on Protection and Rescue," the Ministry of Interior is in charge for seeking and receiving international assistance in case of a disaster, elementary accidents, and other accidents, including health emergencies [1]. According to the "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the period 2018–2023," cooperation also includes also receiving personnel from other countries to respond to emergency situations [2]. Since 2010, Montenegro has been part of the European Union (EU) Civil Protection Mechanism. In 2001, the EU Civil Protection Mechanism was established, fostering cooperation among national civil protection authorities across Europe. The mechanism currently includes all 28 EU Member States in addition to Iceland, Montenegro, Norway, Serbia, North Macedonia, and Turkey. The mechanism was established to enable coordinated assistance from the participating states to victims of natural and man-made disasters in Europe and elsewhere [3]. However, none of these instruments account for how the country plans to facilitate the arrival and movement of foreign personnel during an emergency.

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, "Montenegro has signed 11 bilateral agreements, 2 multilateral agreements and 4 memorandums of cooperation in case of emergencies," while recommending it to develop plans for transportation of medical personnel. It also states that Montenegro, as a member of the North Atlantic Treaty Organization (NATO) member, is able to seek equipment and personnel assistance during emergencies. [4]

Lastly, there is no supporting evidence on the website of the Ministry of Interior, where all ordinances and decisions of the Directorate for Emergency Situations are presented [5]. Further, the websites of the Ministry of Health and Ministry of Defence do not have information about a public plan in place to receive health personnel from other countries to respond to a public health emergency [6, 7].

[1] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zastiti%20i%20spasavanja.pdf>]. Accessed 07 January 2021.

[2] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinami?kim planom aktivnosti za sprovo?enje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[3] European Commission. European Union (EU) Civil Protection Mechanism. [http://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 07 January 2021

[4] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

[5] Ministry of Interior. Directorate for Emergency Situations. "Documents".

[<http://www.mup.gov.me/biblioteka/odluke?pagerIndex=2>]. Accessed 07 January 2021.

[6] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[7] Ministry of Defence. [<https://mod.gov.me/ministarstvo>]. Accessed 07 January 2021.

4.4 HEALTHCARE ACCESS

4.4.1 Access to healthcare

4.4.1a

Does the constitution explicitly guarantee citizens' right to medical care?

Guaranteed free = 4, Guaranteed right = 3, Aspirational or subject to progressive realization = 2, Guaranteed for some groups, not universally = 1, No specific provision = 0

Current Year Score: 3

2020

World Policy Analysis Center

4.4.1b

Access to skilled birth attendants (% of population)

Input number

Current Year Score: 99

2013

WHO/World Bank/United Nations Children's Fund (UNICEF)

4.4.1c

Out-of-pocket health expenditures per capita, purchasing power parity (PPP; current international \$)

Input number

Current Year Score: 530.61

2017

WHO Global Health Expenditure database

4.4.2 Paid medical leave

4.4.2a

Are workers guaranteed paid sick leave?

Paid sick leave = 2, Unpaid sick leave = 1, No sick leave = 0

Current Year Score: 2

2020

World Policy Analysis Center

4.4.3 Healthcare worker access to healthcare

4.4.3a

Has the government issued legislation, a policy, or a public statement committing to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that the Government of Montenegro has issued legislation, a policy, or a public statement committing to provide prioritized health care services to health care workers who become sick as a result of responding to a public health emergency.

The "Law on the Prevention of Population against Infective Diseases" published in 2018 mentions addressing sick health care workers as a result of responding to a public health emergency. Article 36 of the Law states that all programs for the prevention and fight against hospital infections must be based on the "Doctrine of treating the sick, health care workers and associates who are ill with infective diseases or carriers of infective agents of diseases" and "Rules and guidelines for the prevention of the employed against infective diseases and hospital infections." However, no further information for the protection of health care workers responding to public health emergencies is available under this Law [1].

Based on the review of the Master Plan for Development of Health, 2015–2020, the Law on Health Protection, Law on Protection and Rescue, and set of by-laws and ordinances related to civil protection, as well as the website of the Ministry of Health, there are no references related to prioritized health care services to health care workers who become sick as a result of responding to a public health emergency [2, 3, 4, 5, 6]. According to Article 124 of the Law on Health Protection, priorities in the provision of health care are based exclusively on medical indications, taking into account the degree of disability, the severity of the illness or injury, and other circumstances related to the health condition of the citizen [3].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi->

akti/327/1613-10375-28-2-17-3-4.pdf]. Accessed 07 January 2021.

[2] Ministry of Health. 2015. "Master Plan for Development of Health 2015–2020 (Master plan razvoja zdravstva 2015-2020)". [<https://www.gov.me/ResourceManager/FileDownload.aspx?rid=213110&rType=2>]. Accessed 07 January 2021.

[3] Parliament of Montenegro. 2017. "Law on Health Protection (Zakon o zdravstvenoj zaštiti, Sl. CG, 003/16, 039/16, 002/17, 44/2018, 24/2019 - dr. zakoni i 82/2020)". [<https://www.paragraf.me/propisi-crnegore/zakon-o-zdravstvenoj-zastiti.html>]. Accessed 07 January 2021.

[4] Parliament of Montenegro. "Law on Protection and Rescue (Zakon o zaštiti i spašavanju, Sl. CG br. 013/07, 005/08, 086/09, 032/11, 054/16)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=274864&rType=2&file=Zakon%20o%20zastiti%20i%20spasavanju.pdf>]. Accessed 07 January 2021.

[5] Ministry of Interior. "Ordinances". [<http://www.mup.gov.me/biblioteka/pravilnici?pagerIndex=1>]. Accessed 07 January 2021.

[6] Ministry of Health. "Ordinances". [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

4.5 COMMUNICATIONS WITH HEALTHCARE WORKERS DURING A PUBLIC HEALTH EMERGENCY

4.5.1 Communication with healthcare workers

4.5.1a

Is there a system in place for public health officials and healthcare workers to communicate during a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

In Montenegro, there is no evidence of a system in place for public health officials and health care workers to communicate during a public health emergency. According to the "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy, 2018–2023," the collection of all data and communication between all state bodies, including health care workers, is centralized through the pan-European emergency number 112. This number is managed by the Operational Communication Center 112, which is part of the Directorate for Emergency Situations [1]. The pan-European emergency number 112 is the unified communications information system for collecting and unifying data on events by relevant state authorities and emergency services and coordination of all of them [2]. However, there is no indication that the 112 system is used for communication between health care workers and public health officials (e.g., Ministry of Health). Further, the COVID-19 Preparedness and Response Plan does not mention the 112 system as a communication tool [3]. The websites of the Ministry of Health and Interior do not provide additional information about communication between health care workers and public health officials [4, 5]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, while there is both formal and informal communication coordination in the health care system, there are no common communication plans for all hazards. Further, the JEE recommends that Montenegro strengthen IHR-related communication and intersectoral cooperation between public health officials and health care workers on the ground [6].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for implementation of the Strategy for the period 2018-2023 (Strategija za smanjenje rizika od katastrofa sa dinamičkim planom aktivnosti za sprovođenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf].

Accessed 07 January 2021.

- [2] Ministry of Information Society and Telecommunications. 2014. "Ordinance on the Unique European Number "112" for Emergency Calls (Pravilnik o jedinstvenom evropskom broju „112“ za pozive u hitnim slucajevima, 052-01-2644/1-14)". [<http://www.kei.gov.me/ResourceManager/FileDownload.aspx?rid=320753&rType=2&file=Pravilnik%20o%20jedinstvenom%20evropskom%20broju%20E2%80%9E112%E2%80%9C%20za%20pozive%20u%20hitnim%20slu%C4%8Dajevima.pdf>]. Accessed 07 January 2021.
- [3] Government of Montenegro. 2020. "COVID-19 Preparedness and Response Plan (COVID-19 Plan pripremljenosti i odgovora)". [<https://montenegro.un.org/sites/default/files/2020-04/Plan%20pripremljenosti%20i%20odgovora%20-%20Crna%20Gora.pdf>]. Accessed 07 January 2021.
- [4] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [6] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

4.5.1b

Does the system for public health officials and healthcare workers to communicate during an emergency encompass healthcare workers in both the public and private sector?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Montenegro has a system in place for public health officials and health care workers to communicate during a public health emergency in both the public and private sectors. According to the 'Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the period 2018–2023,' a collection of all data and communication between all state bodies, including health care workers is centralised through the pan-European emergency number 112. This number is managed by the Operational Communication Center 112, which is part of the Directorate for Emergency Situations [1]. The pan-European emergency number 112 is the unified communications information system for collecting and unifying data on events by relevant state authorities and emergency services and coordination of all of them [2]. However, there are no references that the number 112 is available to private health workers. However, the Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the period 2018–2023 has envisaged that among the private sector entities that it is possible to establish a team for rescue and protection [1]. Further, there is no additional information about communication of health care workers in both the public and private sector during the emergency situations on the websites of the Ministry of Interior and Ministry of Health [3, 4]. According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, while there is both formal and informal communication coordination in the health care system, there are no common communication plans for all hazards. Further, the JEE recommends that Montenegro strengthen IHR-related communication and intersectoral cooperation between public health officials and health care workers on the ground [5].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamicnim planom aktivnosti za sprovođenje strategije za period 2018-2023. godina)". [http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[2] Ministry of Information Society and Telecommunications. 2014. "Ordinance on the Unique European Number "112" for Emergency Calls (Pravilnik o jedinstvenom evropskom broju „112“ za pozive u hitnim slucajevima, 052-01-2644/1-14)". [<http://www.kei.gov.me/ResourceManager/FileDownload.aspx?rid=320753&rType=2&file=Pravilnik%20o%20jedinstvenom%20evropskom%20broju%20E2%80%9E112%E2%80%9C%20za%20pozive%20u%20hitnim%20slu%C4%8Dajevima.pdf>]. Accessed 07 January 2021.

[3] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

20evropskom%20broju%20%E2%80%9E112%E2%80%9C%20za%20pozive%20u%20hitnim%20slu%C4%8Dajevima.pdf]. Accessed 07 January 2021.

[3] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [<https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y>]. Accessed 26 May 2021.

4.6 INFECTION CONTROL PRACTICES AND AVAILABILITY OF EQUIPMENT

4.6.1 Healthcare associated infection (HCAI) prevention and control programs

4.6.1a

Is there evidence that the national public health system is monitoring for and tracking the number of healthcare associated infections (HCAI) that take place in healthcare facilities?

Yes = 1, No = 0

Current Year Score: 1

In Montenegro, there is evidence of the national public health system monitoring for and tracking the number of health care associated infections that take place in health care facilities.

According to Article 7 of 2018 "Law on the Protection of the Population from Infectious Diseases," everyone has the right to protection against infectious diseases and infections that take place in health care facilities as well as that health care institutions are obliged to cooperate with public institutions in protecting population from infections that take place in health care facilities. In addition, Article 36 mentions infections that take place in health care facilities as one of elements of epidemiological surveillance [1]. The ordinance on the method of notification of infectious diseases, infections that take place in health care facilities, deaths caused by infectious diseases prescribe the manner and deadlines for notification of abovementioned cases [2].

According to media outlets in Montenegro, Escherichia coli and Klebsiella pneumoniae the most problematic infections that take place in health care facilities [3].

In Section 4.5 of the "National Programme for the Control of Antibiotic-resistant Bacteria 2017–2021" calls for cooperation between the National Interdisciplinary Commission for Control of Resistance to Antibiotics and National commission for the Control of Hospital Infections of the Ministry of Health [4].

According to the "Action Plan for Improvement of the System for Supervision and Response on Infectious Diseases 2017–2020," with the "Report on Implemented Activities for period 2015–2017," some of the implemented activities are introduced health case associated infections (HAI) monitoring and further improved monitoring, reporting, and research of HAIs [5].

According to the Joint External Evaluation (JEE) of IHR Core Capacities of Montenegro, conducted in May 2019 and published in March 2021, although there is no national programme for Infection and Prevention and Control (IPC), all health care facilities at secondary and tertiary levels are obliged by law to adopt a program to monitor, prevent, and combat hospital infections. This is implemented through a Commission for the Prevention and Suppression of Hospital Infections, which

submits semi-annual reports to the National Committee for Hospital Infections [6].

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi-akti/327/1613-10375-28-2-17-3-4.pdf>]. Accessed 07 January 2021.

[2] Ministry of Health. 2007. "Ordinance on the Method of Notification of Infectious Diseases, Infections That Take Place in Health Care Facilities, Deaths Caused by Infectious Diseases (Pravilnik o nacinu prijavljivanja zaraznih bolesti, bolnickih infekcija, stanja i smrti oboljelih od zaraznih bolesti)".

[<http://www.uip.gov.me/ResourceManager/FileDownload.aspx?rid=275617&rType=2&file=Pravilnik%20o%20nacinu%20prijavljivanja%20zaraznih%20bolesti%20bolnickih%20infekcija%20stanja.....pdf>]. Accessed 07 January 2021.

[3] CDM. 2017. "Infections That Take Place in Health Care Facilities are Serious Threats."

[<https://m.cdm.me/drustvo/bolnicke-infekcije-ozbiljna-prijetnja/>]. Accessed 07 January 2021.

[4] Government of Montenegro. Ministry of Health. 2016. "National Programme for the Control of Antibiotic-resistant Bacteria 2017–2021 (Strategija za kontrolu rezistencije bakterija na antibiotike 2017-2021)".

[<http://www.gov.me/ResourceManager/FileDownload.aspx?rid=112146&rType=2>]. Accessed 07 January 2021.

[5] Ministry of Health. 2017. "Action Plan for Improvement of the System for Supervision and Response on Infectious Diseases 2017-2020, with the Report on Implemented Activities for period 2015-2017 (Akcioni plan za unapređenje sistema za nadzor i odgovor na zarazne bolesti 2017-2022, sa izvještajem o realizovanim aktivnostima za period 2015-2017. godine)".

[<http://www.gov.me/ResourceManager/FileDownload.aspx?rid=294809&rType=2>] Accessed 07 January 2021.

[6] World Health Organization (WHO). 2019. "Joint External Evaluation of IHR Core Capacities of Montenegro".

[<https://extranet.who.int/sph/sites/default/files/jeeta/Montenegro%20-%20JEE%20Report.pdf>]. Accessed 14 April 2021.

4.7 CAPACITY TO TEST AND APPROVE NEW MEDICAL COUNTERMEASURES

4.7.1 Regulatory process for conducting clinical trials of unregistered interventions

4.7.1a

Is there a national requirement for ethical review (e.g., from an ethics committee or via Institutional Review Board approval) before beginning a clinical trial?

Yes = 1, No = 0

Current Year Score: 1

In Montenegro, there is a national requirement for ethical review (e. g., from an ethics committee approval) before beginning a clinical trial. Prior to the commencement of the conduct of a clinical trial, an applicant for a clinical trial shall submit to the Agency for Medicines and Medical Devices an application with documentation for obtaining approval for a clinical trial. The Agency for Medicines and Medical Devices shall issue the approval after obtaining a positive opinion from the Ethics Committee (there is no information whether the Committee is a permanent body). Conducting clinical trials on medicinal products for human use is in line with the guidance of the European Union (EU) on implementation of good clinical practice [1, 2]. Applications shall be processed by the experts of the advisory body of the Institute and Commission for Clinical Trials, who evaluate clinical trial justifiability and its compliance with Guidelines for Good Clinical Practice. When issuing approvals for clinical trials, a thorough expert assessment shall be done in order to ensure and protect the rights, safety, and well-being of subjects participating in a clinical trial [2].

[1] Ministry of Health. 2013. "Ordinance on the Conditions and Necessary Documentation for Approval and Implementation of Clinical Testing of Medicines for Human Use" (Pravilnik o bližim uslovima i dokumentaciji potrebnoj za odobranje i sprovođenje kliničkih ispitivanja lijekova za upotrebu u humanoj medicini, Sl. CG 02/2014)".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=164462&rType=2&file=Pravilnik%20ispitivanje%20ljekova%20humana%20medicina.pdf>]. Accessed 07 January 2021.

[2] Agency for Medicines and Medical Devices. "Clinical Trials, Responsibilities".

[https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=5526059938915504¶mPut=+%3E+Clinical+Trials+%3E+Activities¶mRender=2¶mS=85&_adf.ctrl-state=2mtswndms_220]. Accessed 07 January 2021.

4.7.1b

Is there an expedited process for approving clinical trials for unregistered medical countermeasures (MCM) to treat ongoing epidemics?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that there is an expedited process in Montenegro for approving clinical trials for unregistered medical countermeasures to treat ongoing pandemics. Based on a review of the Ordinance on the Conditions and Necessary Documentation for Approval and Implementation of Clinical Testing of Medicines for Human Use, an expedited process does not exist [1]. In addition, there is no available form on the website of the Agency for Medicines and Medical Devices related to expedited review [2]. The websites of the Ministry of Health and Ministry of Science do not have information regarding an expedited process for approving clinical trials for unregistered medical countermeasures to treat ongoing pandemics [3, 4].

[1] Ministry of Health. 2013. "Ordinance on the Conditions and Necessary Documentation for Approval and Implementation of Clinical Testing of Medicines for Human Use" (Pravilnik o bližim uslovima i dokumentaciji potrebnoj za odobranje i sprovođenje kliničkih ispitivanja lijekova za upotrebu u humanoj medicini, Sl. CG 02/2014)".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=164462&rType=2&file=Pravilnik%20ispitivanje%20ljekova%20humana%20medicina.pdf>]. Accessed 07 January 2021.

[2] Agency for Medicines and Medical Devices. "Clinical Trials, Responsibilities".

[https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=5526059938915504¶mPut=+%3E+Clinical+Trials+%3E+Activities¶mRender=2¶mS=85&_adf.ctrl-state=2mtswndms_220]. Accessed 07 January 2021.

[3] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Education, Science, Culture and Sport. [<https://mps.gov.me/ministarstvo>]. Accessed 07 January 2021.

4.7.2 Regulatory process for approving medical countermeasures

4.7.2a

Is there a government agency responsible for approving new medical countermeasures (MCM) for humans?

Yes = 1 , No = 0

Current Year Score: 1

In Montenegro, the Agency for Medicines and Medical Devices is a government agency responsible for approving new medical countermeasures for humans. Some of the responsibilities of the Agency are issues manufacturing and marketing authorizations for medicines for human use, establishes and organizes pharmacovigilance system with the aim of monitoring safety of medicines on the market and detection of any change in terms of the benefit-risk ratio of their administration; issues approval for clinical trials of medicines without marketing authorization; decides on amendments to the approval—

that is, to the protocol of clinical trials; keeps records of clinical trials of medicines that have marketing authorization; controls conduct of clinical trials; issues certification on the application of good manufacturing practice, good clinical practice, and other certificates according to this law; issues certificates required for export of medicines according to the recommendations of the World Health Organization (WHO); approves supply—that is, import of medicines without marketing authorization and medicines intended for scientific and medical research for further processing or for the treatment of an individual patient or a group of patients as well as other medicines according to this law [1]. Further, the website of the Agency for Medicines and Medical Devices contains information on the medicines for which the Agency has issued approval for human use or those that are registered in Montenegro [2].

[1] Agency for Medicines and Medical Devices. "Activities".

[https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=5526456793096619¶mPut=About+Institute+%3E+Activities¶mRender=2¶mS=5&_adf.ctrl-state=2mtswndms_254]. Accessed 07 January 2021.

[2] Agency for Medicines and Medical Devices. "Register of Medicines for Human Use".

[https://www.cinmed.me/Portal/faces/registarHumani?_adf.ctrl-state=2mtswndms_254&_afLoop=5526487531820866]. Accessed 07 January 2021.

4.7.2b

Is there an expedited process for approving medical countermeasures (MCM) for human use during public health emergencies?

Yes = 1 , No = 0

Current Year Score: 0

In Montenegro, there is no evidence of an expedited process for approving medical countermeasures for human use during public health emergencies. According to the "Ordinance on the Conditions and Necessary Documentation for Approval and Implementation of Clinical Testing of Medicines for Human Use," there is no expedited process for approving medical countermeasures for human use during public health emergencies. In addition, there is no available form on the website of the Agency for Medicines and Medical Devices to request an expedited review [1, 2]. The websites of the Ministry of Health and Ministry of Science do not contain information related to an expedited process for approving medical countermeasures for human use during public health emergencies [3, 4].

[1] Ministry of Health. 2013. "Ordinance on the Conditions and Necessary Documentation for Approval and Implementation of Clinical Testing of Medicines for Human Use" (Pravilnik o bližim uslovima i dokumentaciji potrebnoj za odobranje i sprovođenje kliničkih ispitivanja lijekova za upotrebu u humanoj medicini, Sl. CG 02/2014)".

[<http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=164462&rType=2&file=Pravilnik%20ispitivanje%20ljekova%20humana%20medicina.pdf>]. Accessed 07 January 2021.

[2] Agency for Medicines and Medical Devices. "Clinical Trials, Responsibilities".

[https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=5526059938915504¶mPut=%3E+Clinical+Trials+%3E+Activities¶mRender=2¶mS=85&_adf.ctrl-state=2mtswndms_220]. Accessed 07 January 2021.

[3] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Education, Science, Culture, and Sport. [<https://mps.gov.me/ministarstvo>]. Accessed 07 January 2021.

Category 5: Commitments to improving national capacity, financing plans to address gaps, and adhering to global norms

5.1 INTERNATIONAL HEALTH REGULATIONS (IHR) REPORTING COMPLIANCE AND DISASTER RISK REDUCTION

5.1.1 Official IHR reporting

5.1.1a

Has the country submitted IHR reports to the WHO for the previous calendar year?

Yes = 1 , No = 0

Current Year Score: 1

2020

World Health Organization

5.1.2 Integration of health into disaster risk reduction

5.1.2a

Are epidemics and pandemics integrated into the national risk reduction strategy or is there a standalone national disaster risk reduction strategy for epidemics and pandemics?

Yes = 1 , No = 0

Current Year Score: 1

In Montenegro, pandemics are integrated into the national risk reduction strategy. Montenegro has a document entitled the "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023" elaborates biological hazards, which include infectious disease epidemics and epizootic diseases within its section that outlines the disaster risks to the country (in Section 3.1.3 of the document). In addition to diseases that are registered in a smaller or larger number every year in the territory of Montenegro, this document also refers to the possibility of "imported cases," primarily believed to be extremely dangerous infectious diseases (diseases that spread rapidly and/or have high aviation), such as SARS, bird flu, quarantine diseases such as the plague and hemorrhagic fever, variations of the human pandemic flu, etc. Section 4 of the strategy presents organizational set up of the system for protection and rescue, Section 5 elaborates the strategic direction for risk reduction of emergency situations, and Section 6 defines vision and strategic direction for developing a system of rescue and protection [1].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023 (Strategija za smanjenje rizika od katastrofa sa dinamikim planom aktivnosti za sprovedenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf].

Accessed 07 January 2021.

5.2 CROSS-BORDER AGREEMENTS ON PUBLIC HEALTH AND ANIMAL HEALTH EMERGENCY RESPONSE

5.2.1 Cross-border agreements

5.2.1a

Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to public health emergencies?

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

Current Year Score: 2

Montenegro has cross-border agreements, protocols, and memorandums of understanding (MOUs) with neighboring countries with regard to public health emergencies and there is no evidence of gaps in implementation. The "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023" mentions bilateral agreements with the following neighboring countries: Serbia, Bosnia and Herzegovina, and Croatia as well as a memorandum of understanding (MoU) with Italy. These agreements regulate planning and implementation of preventive measures for protection against natural, technical, and technological accidents and civilization disasters (including health emergencies). The agreements also regulate mutual notification of emergency situations, their occurrence, and the consequences as well as mutual assistance in protection and rescue in case of emergency situations, etc. [1]. Since 2010, Montenegro is part of the "EU Civil Protection Mechanism." In 2001, the EU Civil Protection Mechanism was established, fostering cooperation among national civil protection authorities across Europe. The mechanism currently includes all 28 EU Member States in addition to Iceland, Montenegro, Norway, Serbia, North Macedonia, and Turkey. The mechanism was set up to enable coordinated assistance from the participating states to victims of natural and man-made disasters in Europe and elsewhere [2]. There is no information regarding gaps in the implementation of these agreements on the websites of the Ministry of Health, Ministry of Interior, and media outlets [3, 4].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for the Implementation of the Strategy for the Period 2018-2023 (Strategija za smanjenje rizika od katastrofa sa dinamicnim planom aktivnosti za sprovedenje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf].

Accessed 07 January 2021.

[2] European Commission. "EU Civil Protection Mechanism". [http://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 07 January 2021.

[3] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

5.2.1b

Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to animal health emergencies?

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

Current Year Score: 2

Montenegro has cross-border agreements, protocols, and memorandums of understanding (MOUs) with neighboring countries with regard to animal health emergencies and there are no evidence of gaps in implementation. The "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018–2023"

mentions bilateral agreements with Serbia, Bosnia and Herzegovina, and Croatia as well as an MoU with Italy. These agreements regulate the planning and implementation of preventive measures for protection against natural, technical, and technological accidents and civilization disasters (including health emergencies). The agreements also regulate mutual notification of emergency situations, their occurrence, and the consequences as well as mutual assistance in protection and rescue in case of emergency situations, etc. [1]. One of the agreements that is publicly available, the "Agreement between Government of Serbia and Government of Montenegro on Veterinary Affairs," also includes cooperation between the states in issues related to animal health emergencies. The agreement envisages that two sides will, within 24 hours, inform the other side about the occurrence of contagious animal diseases in accordance with the method of reporting the occurrence of a disease prescribed by the World Organization for Animal Health (OIE). Moreover, the two sides will provide mutual assistance in the production and procurement of the necessary means for the suppression of diseases and the treatment of animals [2]. Further, since 2010, Montenegro is part of the EU Civil Protection Mechanism. In 2001, the "EU Civil Protection Mechanism" was established, fostering cooperation among national civil protection authorities across Europe. The Mechanism currently includes all 28 EU Member States, in addition to Iceland, Montenegro, Norway, Serbia, North Macedonia, and Turkey. The mechanism was established to enable coordinated assistance from the participating states to victims of natural and man-made disasters in Europe and elsewhere [3]. There is no information on the gaps in implementation of these agreements on the websites of the Ministry of Health, Ministry of Interior, and media outlets [4, 5].

[1] Ministry of Interior. 2017. "Strategy for Disaster Risk Reduction with Dynamic Plan of Activities for Implementation of the Strategy for the Period 2018-2023 (Strategija za smanjenje rizika od katastrofa sa dinami?kim planom aktivnosti za sprovo?enje strategije za period 2018-2023. godina)".

[http://www.gsv.gov.me/ResourceManager/FileDownload.aspx?rid=296391&rType=2&file=7_55_21_12_2017.pdf]. Accessed 07 January 2021.

[2] Government of Montenegro. 2012. "Agreement between Government of Serbia and Government of Montenegro on Veterinary Affairs (Sprazum izmedju Vlade Republike Srbije i Vlade Crne Gore u oblasti veterine)".

[http://www.gov.me/ResourceManager/FileDownload.aspx?rid=116181&rType=2&file=10_87_08_11_2012.pdf&alphabet=cyr]. Accessed 07 January 2021.

[3] European Commission. "EU Civil Protection Mechanism". [http://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 07 January 2021.

[4] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

5.3 INTERNATIONAL COMMITMENTS

5.3.1 Participation in international agreements

5.3.1a

Does the county have signatory and ratification (or same legal effect) status to the Biological Weapons Convention?

Signed and ratified (or action having the same legal effect) = 2, Signed = 1, Non-compliant or not a member = 0

Current Year Score: 2

2021

Biological Weapons Convention

5.3.1b

Has the country submitted confidence building measures for the Biological Weapons Convention in the past three years?

Yes = 1 , No = 0

Current Year Score: 1

2021

Biological Weapons Convention

5.3.1c

Has the state provided the required United Nations Security Council Resolution (UNSCR) 1540 report to the Security Council Committee established pursuant to resolution 1540 (1540 Committee)?

Yes = 1 , No = 0

Current Year Score: 1

2021

Biological Weapons Convention

5.3.1d

Extent of United Nations Security Council Resolution (UNSCR) 1540 implementation related to legal frameworks and enforcement for countering biological weapons:

Very good (60+ points) = 4, Good (45–59 points) = 3, Moderate (30–44 points) = 2, Weak (15–29 points) = 1, Very weak (0–14 points) or no matrix exists/country is not party to the BWC = 0

Current Year Score: 3

2021

Biological Weapons Convention

5.3.2 Voluntary memberships

5.3.2a

Does the country meet at least 2 of the following criteria?

- Membership in Global Health Security Agenda (GHSA)
- Membership in the Alliance for Country Assessments for Global Health Security and IHR Implementation (JEE Alliance)
- Membership in the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP)
- Membership in the Australia Group (AG)
- Membership in the Proliferation Security Initiative (PSI)

Needs to meet at least two of the criteria to be scored a 1 on this measure. , Yes for five = 1 , Yes for four = 1 , Yes for three = 1 , Yes for two = 1 , Yes for one = 0 , No for all = 0

Current Year Score: 0

2021

Global Health Security Agenda; JE Alliance; Global Partnership; Australia Group; PSI

5.4 JOINT EXTERNAL EVALUATION (JEE) AND PERFORMANCE OF VETERINARY SERVICES PATHWAY (PVS)

5.4.1 Completion and publication of a Joint External Evaluation (JEE) assessment and gap analysis

5.4.1a

Has the country completed a Joint External Evaluation (JEE) or precursor external evaluation (e.g., GHSA pilot external assessment) and published a full public report in the last five years?

Yes = 1 , No = 0

Current Year Score: 1

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.4.1b

Has the country completed and published, within the last five years, either a National Action Plan for Health Security (NAPHS) to address gaps identified through the Joint External Evaluation (JEE) assessment or a national GHSA roadmap that sets milestones for achieving each of the GHSA targets?

Yes = 1 , No = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.4.2 Completion and publication of a Performance of Veterinary Services (PVS) assessment and gap analysis

5.4.2a

Has the country completed and published a Performance of Veterinary Services (PVS) assessment in the last five years?

Yes = 1 , No = 0

Current Year Score: 0

2021

OIE PVS assessments

5.4.2b

Has the country completed and published a Performance of Veterinary Services (PVS) gap analysis in the last five years?

Yes = 1, No = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5 FINANCING

5.5.1 National financing for epidemic preparedness

5.5.1a

Is there evidence that the country has allocated national funds to improve capacity to address epidemic threats within the past three years?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that Montenegro has allocated national funds to improve capacity to address epidemic threats within the past three years. Based on the analysis of the national budget for 2018, 2019, and 2020, it can be confirmed that the state has allocation to improve capacity to address emergency situations, but it cannot be confirmed that these allocations include funds to improve capacity to address epidemic threats [1, 2, 3]. There is no additional information regarding national funds to improve capacity to address epidemic threats within the past three years on the websites of the Ministry of Finance, Ministry of Health, Ministry of Agriculture, and Ministry of Interior [4, 5, 6, 7].

[1] Ministry of Finance and Social Protection. 2019. "Law on Budget for 2020 (Zakon o budzetu za 2020, "Sl. list CG", br. 74/2019 i 61/2020) [<https://www.paragraf.me/propisi-crnegore/zakon-o-budzetu-crne-gore.html>]. Accessed 07 January 2021.

[2] Ministry of Finance and Social Protection. 2018. "Law on Budget for 2019 (Zakon o budzetu za 2019, 01-1976/2)". [<https://mif.gov.me/ResourceManager/FileDownload.aspx?rid=354104&rType=2&file=Zakona%20o%20budzetu%20za%202019.godinu.pdf>]. Accessed 07 January 2021.

[3] Ministry of Finance and Social Protection. 2017. "Law on Budget for 2018 (Zakon o budzetu za 2018)". [<https://www.mif.gov.me/ResourceManager/FileDownload.aspx?rid=297452&rType=2&file=Zakon%20o%20budzetu%20Crne%20Gore%20za%202018%20godinu.pdf>]. Accessed 07 January 2021.

[4] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.

[6] Ministry of Finance and Social Protection. [<https://mif.gov.me/ministarstvo>]. Accessed 07 January 2021.

[7] Ministry of Agriculture, Forestry, and Water Management. [<https://mpr.gov.me/ministarstvo>]. Accessed 07 January 2021.

5.5.2 Financing under Joint External Evaluation (JEE) and Performance of Veterinary Services (PVS) reports and gap analyses

5.5.2a

Does the Joint External Evaluation (JEE) report, National Action Plan for Health Security (NAPHS), and/or national GHSA roadmap allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a JEE = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.5.2b

Does the Performance of Veterinary Services (PVS) gap analysis and/or PVS assessment allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a PVS = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5.3 Financing for emergency response

5.5.3a

Is there a publicly identified special emergency public financing mechanism and funds which the country can access in the face of a public health emergency (such as through a dedicated national reserve fund, an established agreement with the World Bank pandemic financing facility/other multilateral emergency funding mechanism, or other pathway identified through a public health or state of emergency act)?

Yes = 1 , No = 0

Current Year Score: 0

In Montenegro, there is no publicly identified special emergency public financing mechanism or funds that the country can access in the face of a public health emergency. The national budget of Montenegro has allocation for emergency situations, but it cannot be confirmed that these funds also include a public health emergency [1, 2, 3]. The websites of the Ministry of Finance, Ministry of Health, and Ministry of Interior do not have information about special emergency public financing mechanisms or funds which the country can access in the event of a public health emergency [4, 5, 6]. Further, Montenegro is not an IDA eligible country [7]. Montenegro is one of the beneficiaries outside of the European Union (EU) of the EU civil protection mechanism, whose objective is to strengthen cooperation in the field of civil protection with a view to improve prevention, preparedness, and response to disasters [8].

- [1] Ministry of Finance and Social Protection. 2019. "Law on Budget for 2020 (Zakon o budzetu za 2020, "Sl. list CG", br. 74/2019 i 61/2020)". [<https://www.paragraf.me/propisi-crnegore/zakon-o-budzetu-crne-gore.html>]. Accessed 07 January 2021.
- [2] Ministry of Finance and Social Protection. 2018. "Law on Budget for 2019 (Zakon o budzetu za 2019, 01-1976/2)". [<https://mif.gov.me/ResourceManager/FileDownload.aspx?rid=354104&rType=2&file=Zakona%20o%20budzetu%20za%202019.godinu.pdf>]. Accessed 07 January 2021.
- [3] Ministry of Finance and Social Protection. 2017. "Law on Budget for 2018 (Zakon o budzetu za 2018)". [<https://www.mif.gov.me/ResourceManager/FileDownload.aspx?rid=297452&rType=2&file=Zakon%20o%20budzetu%20Crne%20Gore%20za%202018%20godinu.pdf>]. Accessed 07 January 2021.
- [4] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [5] Ministry of Interior. [<https://mup.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [6] Ministry of Finance and Social Protection. [<https://mif.gov.me/ministarstvo>]. Accessed 07 January 2021.
- [7] IDA. "Borrowing Countries". [<https://ida.worldbank.org/about/borrowing-countries>]. Accessed 07 January 2021.
- [8] European Union (EU) Civil Protection Mechanism. [https://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 07 January 2021.

5.5.4 Accountability for commitments made at the international stage for addressing epidemic threats

5.5.4a

Is there evidence that senior leaders (president or ministers), in the past three years, have made a public commitment either to:

- Support other countries to improve capacity to address epidemic threats by providing financing or support?
- Improve the country's domestic capacity to address epidemic threats by expanding financing or requesting support to improve capacity?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

There is no evidence that senior leaders in government have made public commitments to support other countries to improve capacity to address epidemic threats by providing financing or support or to improve the country's domestic capacity to address epidemic threats by expanding financing or requesting support to improve capacity.

The political leaders of Montenegro have not made a public commitment in the past three years to improve the country's domestic capacity to address epidemic threats by requesting support to improve capacity. However, Montenegro requested assistance through the North Atlantic Treaty Organization's (NATO) Euro-Atlantic Disaster Response Coordination Centre (EADRCC) for surgical masks, protective suits, and other equipment on 30 March to fight COVID-19 pandemic [1]. There is no evidence that senior leaders in Montenegro have made a public commitment either to support other countries to improve capacity to address epidemic threats by providing financing or support in the past three years. The websites of the Ministries of Health, Ministry of Foreign Affairs, and the World Health Organization (WHO) do not provide evidence of such commitments [2, 3, 4].

[1] North Atlantic Treaty Organization (NATO). "Montenegro Requests International Assistance in their Response to COVID-19". [https://www.nato.int/cps/en/natohq/news_174576.htm?]. Accessed 07 January 2021.

[2] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[3] Ministry of Foreign Affairs. [<https://mvp.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] World Health Organization (WHO). "Montenegro". [<https://www.euro.who.int/en/countries/montenegro>]. Accessed 07

January 2021

5.5.4b

Is there evidence that the country has, in the past three years, either:

- Provided other countries with financing or technical support to improve capacity to address epidemic threats?
- Requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is evidence that Montenegro has requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats. The Global Health Security Funding Tracker notes that Montenegro has received funding from multiple donors to enhance their capacity on global security preparedness. In the period 2014–2020, Montenegro has received US\$ 14.86 million [1]. In addition, during COVID-19 outbreak, Montenegro requested assistance through NATO's Euro-Atlantic Disaster Response Coordination Centre (EADRCC) for surgical masks, protective suits, and other equipment to fight COVID-19 pandemic [2]. However, the websites of the Global Health Security Funding Tracker and websites of the Ministries of Health and Ministry of Foreign Affairs as well as the World Health Organization's (WHO) website do not have information about providing other countries with financing or technical support to improve capacity to address epidemic threats [1, 3, 4, 5].

[1] Global Health Security Funding Tracker. [<https://tracking.ghscosting.org/details/1003/recipient>]. Accessed 23 April 2021.

[2] North Atlantic Treaty Organization (NATO). "Montenegro Requests International Assistance in their Response to COVID-19". [https://www.nato.int/cps/en/natohq/news_174576.htm?]. Accessed 07 January 2021.

[3] Ministry of Health. [<https://mzd.gov.me/ministarstvo>]. Accessed 07 January 2021.

[4] Ministry of Foreign Affairs. [<https://mvp.gov.me/ministarstvo>]. Accessed 07 January 2021.

[5] World Health Organization (WHO). "Montenegro". [<https://www.euro.who.int/en/countries/montenegro>]. Accessed 07 January 2021

5.5.4c

Is there evidence that the country has fulfilled its full contribution to the WHO within the past two years?

Yes = 1, No = 0

Current Year Score: 1

2021

Economist Impact analyst qualitative assessment based on official national sources, which vary by country

5.6 COMMITMENT TO SHARING OF GENETIC AND BIOLOGICAL DATA AND SPECIMENS

5.6.1 Commitment to sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) in both emergency and nonemergency research

5.6.1a

Is there a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence of a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza.

Article 16 of the "Law on the Protection of the Population from Infectious Diseases Institute for Public Health" monitors and studies the movement of infectious diseases in accordance with international acts and programs of the World Health Organization (WHO) as well as informs competent authorities and other entities in the country and abroad for the purpose of early warning and exchange of information [1].

The "Action Plan for Improvement of System for Supervision and Response on Infectious Diseases 2017-2022," with the Report on Implemented Activities for the period 2015–2017, under Activity 1.3, envisages exchange of data with the European Centre for Disease Prevention and Control [2].

According to the statement of the Directorate for Food Safety, Veterinary, and Phytosanitary Affairs from 2017, Montenegro has begun collecting and submitting data to the European Food Safety Authority predominantly on zoonosis, antimicrobial resistance, food poisoning, veterinary residues, as well as expanding national capacity to assess and communicate risk [3].

The European Centre for Disease Prevention and Control has relevant data related to Montenegro that goes beyond influenza, which confirms the Montenegrin commitment to sharing genetic data, epidemiological data, clinical specimens, and/or isolated specimens (biological materials) with international organizations and/or other countries that goes beyond influenza [4].

The websites of the Ministry of Health and Ministry of Agriculture provide no additional information regarding a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza [5, 6].

There is no information on international cooperation on sharing genetic or specimen data in the Joint External Evaluation of IHR Core Capacities of Montenegro. [7]

[1] Parliament of Montenegro. 2018. "Law on the Protection of the Population from Infectious Diseases (Zakon o zaštiti stanovništva od zaraznih bolesti, Broj: 28-2/17-3/4)". [<http://zakoni.skupstina.me/zakoni/web/dokumenta/zakoni-i-drugi->

akti/327/1613-10375-28-2-17-3-4.pdf]. Accessed 07 January 2021.

[2] Ministry of Health. 2017. "Action Plan for Improvement of System for Supervision and Response on Infectious Diseases 2017–2022, with the Report on Implemented Activities for the Period 2015–2017 (Akcioni plan za unapre?enje sistema za nadzor i odgovor na zarazne bolesti 2017-2022, sa Izvještajem o realizovanim aktivnostima za period 2015-2017. godine)". [http://www.gov.me/ResourceManager/FileDownload.aspx?rid=294809&rType=2]. Accessed 07 January 2021.

[3] Directorate for Food Safety, Veterinary and Phitosanitary Affairs. "Information—Montenegro has Started Collecting and Submitting Data to EFSA". [http://www.ubh.gov.me/uprava/medjunarodnasaradnja/171373/Obavjestenje-Crna-Gora-po-prvi-put-dostavila-podatke-EFSA-i.html]. Accessed 07 January 2021.

[4] European Center for Diseases Prevention. "Table. Transmission of West Nile Fever, May to November 2013—Table of Cases, 2013". [https://ecdc.europa.eu/en/publications-data/table-transmission-west-nile-fever-may-november-2013-table-cases-2013]. Accessed 07 January 2021.

[5] Ministry of Health. [http://www.mzdravlja.gov.me/ministarstvo]. Accessed 07 January 2021.

[6] Ministry of Agriculture, Forestry, and Water Management. [https://mpr.gov.me/ministarstvo]. Accessed 07 January 2021.

[7] World Health Organization (WHO). March 17, 2021. "Joint External Evaluation of IHR Core Capacities of Montenegro: Mission Report, 27–31 May 2019". [https://apps.who.int/iris/bitstream/handle/10665/340196/9789240018228-eng.pdf?sequence=1&isAllowed=y]. Accessed 26 May 2021.

5.6.1b

Is there public evidence that the country has not shared samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years?

Yes = 0 , No = 1

Current Year Score: 1

There is no public evidence that the country has not shared samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years. There is no evidence of non-sharing of samples in accordance with the PIP framework in the "Review of the Pandemic Influenza Preparedness Framework" issued by World Health Organization (WHO) in 2017 as well as the WHO website [1, 2]. In addition, there is no media coverage stating that Montenegro has not shared influenza samples.

[1] World Health Organization. "Review of the Pandemic Influenza Preparedness Framework". [https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf]. Accessed 07 January 2021.

[2] World Health Organization. [http://www.who.int]. Accessed 07 January 2021.

5.6.1c

Is there public evidence that the country has not shared pandemic pathogen samples during an outbreak in the past two years?

Yes = 0 , No = 1

Current Year Score: 1

There is no public evidence that the country has not shared pandemic pathogen samples during an outbreak in the past two years. Further, there is no evidence that Montenegro has not shared pandemic pathogen samples during an outbreak in the past two years in the review of information from the reports of the World Health Organization (WHO) as well as its website and media coverage [1, 2]. There is no evidence that Montenegro has not shared COVID-19 samples during the pandemic [3].

- [1] World Health Organization. "Review of the Pandemic Influenza Preparedness Framework". [https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf]. Accessed 07 January 2021.
- [2] World Health Organization. [http://www.who.int]. Accessed 07 January 2021.
- [3] World Health Organization. "COVID-19 Dashboard". [https://covid19.who.int/?gclid=EAlalQobChMI-5Tx1ua37gIVCJ7VCh3qugoYEAAYASAAEgK_H_D_BwE]. Accessed 07 January 2021

Category 6: Overall risk environment and vulnerability to biological threats

6.1 POLITICAL AND SECURITY RISK

6.1.1 Government effectiveness

6.1.1a

Policy formation (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1b

Quality of bureaucracy (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 1

2020

Economist Intelligence

6.1.1c

Excessive bureaucracy/red tape (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1d

Vested interests/cronyism (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 0

2020

Economist Intelligence

6.1.1e

Country score on Corruption Perception Index (0-100, where 100=best)

Input number

Current Year Score: 45

2020

Transparency International

6.1.1f

Accountability of public officials (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1g

Human rights risk (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.2 Orderly transfers of power

6.1.2a

How clear, established, and accepted are constitutional mechanisms for the orderly transfer of power from one government to another?

Very clear, established and accepted = 4, Clear, established and accepted = 3, One of the three criteria (clear, established, accepted) is missing = 2, Two of the three criteria (clear, established, accepted) are missing = 1, Not clear, not established, not accepted = 0

Current Year Score: 2

2021

Economist Intelligence

6.1.3 Risk of social unrest

6.1.3a

What is the risk of disruptive social unrest?

Very low: Social unrest is very unlikely = 4, Low: There is some prospect of social unrest, but disruption would be very limited = 3, Moderate: There is a considerable chance of social unrest, but disruption would be limited = 2, High: Major social unrest is likely, and would cause considerable disruption = 1, Very high: Large-scale social unrest on such a level as to seriously challenge government control of the country is very likely = 0

Current Year Score: 1

2021

Economist Intelligence

6.1.4 Illicit activities by non-state actors

6.1.4a

How likely is it that domestic or foreign terrorists will attack with a frequency or severity that causes substantial disruption?

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

Current Year Score: 3

2021

Economist Intelligence

6.1.4b

What is the level of illicit arms flows within the country?

4 = Very high, 3 = High, 2 = Moderate, 1 = Low, 0 = Very low

Current Year Score: 2

2020

UN Office of Drugs and Crime (UNODC)

6.1.4c

How high is the risk of organized criminal activity to the government or businesses in the country?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.1.5 Armed conflict

6.1.5a

Is this country presently subject to an armed conflict, or is there at least a moderate risk of such conflict in the future?

No armed conflict exists = 4, Yes; sporadic conflict = 3, Yes; incursional conflict = 2, Yes, low-level insurgency = 1, Yes; territorial conflict = 0

Current Year Score: 3

2021

Economist Intelligence

6.1.6 Government territorial control

6.1.6a

Does the government's authority extend over the full territory of the country?

Yes = 1, No = 0

Current Year Score: 1

2021

Economist Intelligence

6.1.7 International tensions

6.1.7a

Is there a threat that international disputes/tensions could have a negative effect?

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

Current Year Score: 2

2021

Economist Intelligence

6.2 SOCIO-ECONOMIC RESILIENCE

6.2.1 Literacy

6.2.1a

Adult literacy rate, population 15+ years, both sexes (%)

Input number

Current Year Score: 98.85

2018

United Nations Development Programme (UNDP); United Nations Educational, Scientific and Cultural Organization (UNESCO);
The Economist Intelligence Unit

6.2.2 Gender equality

6.2.2a

United Nations Development Programme (UNDP) Gender Inequality Index score

Input number

Current Year Score: 0.88

2018

United Nations Development Programme (UNDP); The Economist Intelligence Unit

6.2.3 Social inclusion

6.2.3a

Poverty headcount ratio at \$1.90 a day (2011 PPP) (% of population)

Input number

Current Year Score: 0.3

2015

World Bank; Economist Impact

6.2.3b

Share of employment in the informal sector

Greater than 50% = 2, Between 25-50% = 1, Less than 25% = 0

Current Year Score: 1

According to the project "Employment and Social Affairs Platforms" implemented by the Regional Cooperation Council, employment in the informal sector in the Western Balkans is considered to be between 18.1% and 33% [1, 2]. The Economic Reform Program, 2020–2022 and data from the Montenegro Statistical Office (MONSTAT) do not provide information about

informal employment in Montenegro [3]. Further, the World Bank does not provide information about informal employment in Montenegro [4].

[1] Regional Cooperation Council. [https://www.rcc.int/priority_areas/27/employment-and-social-affairs-platform-esap-2]. Accessed 07 January 2021.

[2] Radio slobodna Evropa. "Informal Employment in the Western Balkans is Between 18 and 33 percent". [<https://www.slobodnaevropa.org/a/29906251.html>]. Accessed 07 January 2021.

[3] Government of Montenegro. January 2020. "Economic Reform Programme 2020-2022". [<https://www.gov.me/ResourceManager/FileDownload.aspx?rid=396260&rType=2>]. Accessed 07 January 2021.

[4] Montenegro Statistical Office (MONSTAT). Labor Force Survey. [<https://www.monstat.org/cg/page.php?id=22&pageid=22>]. Accessed 07 January 2021.

[5] World Bank. "Informal Employment". [<https://data.worldbank.org/indicator/SL.ISV.IFRM.ZS>]. Accessed 07 January 2021.

6.2.3c

Coverage of social insurance programs (% of population)

Scored in quartiles (0-3, where 3=best)

Current Year Score: 3

2016, or latest available

World Bank; Economist Impact calculations

6.2.4 Public confidence in government

6.2.4a

Level of confidence in public institutions

Input number

Current Year Score: 1

2021

Economist Intelligence Democracy Index

6.2.5 Local media and reporting

6.2.5a

Is media coverage robust? Is there open and free discussion of public issues, with a reasonable diversity of opinions?

Input number

Current Year Score: 1

2021

Economist Intelligence Democracy Index

6.2.6 Inequality

6.2.6a

Gini coefficient

Scored 0-1, where 0=best

Current Year Score: 0.39

Latest available.

World Bank; Economist Impact calculations

6.3 INFRASTRUCTURE ADEQUACY

6.3.1 Adequacy of road network

6.3.1a

What is the risk that the road network will prove inadequate to meet needs?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.3.2 Adequacy of airports

6.3.2a

What is the risk that air transport will prove inadequate to meet needs?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.3.3 Adequacy of power network

6.3.3a

What is the risk that power shortages could be disruptive?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.4 ENVIRONMENTAL RISKS

6.4.1 Urbanization

6.4.1a

Urban population (% of total population)

Input number

Current Year Score: 67.15

2019

World Bank

6.4.2 Land use

6.4.2a

Percentage point change in forest area between 2006–2016

Input number

Current Year Score: 2.99

2008-2018

World Bank; Economist Impact

6.4.3 Natural disaster risk

6.4.3a

What is the risk that the economy will suffer a major disruption owing to a natural disaster?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.5 PUBLIC HEALTH VULNERABILITIES

6.5.1 Access to quality healthcare

6.5.1a

Total life expectancy (years)

Input number

Current Year Score: 76.77

2018

United Nations; World Bank, UNICEF; Institute for Health Metrics and Evaluation (IHME); Central Intelligence Agency (CIA)
World Factbook

6.5.1b

Age-standardized NCD mortality rate (per 100 000 population)

Input number

Current Year Score: 603.1

2019

WHO

6.5.1c

Population ages 65 and above (% of total population)

Input number

Current Year Score: 15.39

2019

World Bank

6.5.1d

Prevalence of current tobacco use (% of adults)

Input number

Current Year Score: 27.43

2018

World Bank

6.5.1e

Prevalence of obesity among adults

Input number

Current Year Score: 23.3

2016

WHO

6.5.2 Access to potable water and sanitation

6.5.2a

Percentage of homes with access to at least basic water infrastructure

Input number

Current Year Score: 97.04

2017

UNICEF; Economist Impact

6.5.2b

Percentage of homes with access to at least basic sanitation facilities

Input number

Current Year Score: 97.77

2017

UNICEF; Economist Impact

6.5.3 Public healthcare spending levels per capita

6.5.3a

Domestic general government health expenditure per capita, PPP (current international \$)

Input number

Current Year Score: 1026.98

2018

WHO Global Health Expenditure database

6.5.4 Trust in medical and health advice

6.5.4a

Trust medical and health advice from the government

Share of population that trust medical and health advice from the government , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 0

2018

Wellcome Trust Global Monitor 2018

6.5.4b

Trust medical and health advice from medical workers

Share of population that trust medical and health advice from health professionals , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 1

2018

Wellcome Trust Global Monitor 2018