ECDC accession support to the Western Balkans and Türkiye

ECDC country visit to Montenegro to discuss surveillance of communicable diseases

September 2023

Introduction

ECDC is helping countries in the Western Balkans and Türkiye to improve their infectious disease prevention and control systems and public health workforce in order to prepare them for their future participation in ECDC work.

Technical cooperation with Western Balkans and Türkiye aims to improve their 'One-Health' response to antimicrobial resistance (AMR) and enhance surveillance of laboratory-confirmed severe acute respiratory infections (SARI). The project is funded by the European Commission (DG NEAR) under the Instrument of Pre-accession Assistance (IPA).

This action is structured around three technical work streams. 'Work Stream 1: Preparatory measures to enable IPA beneficiaries to participate in ECDC activities and systems'. The aim is to support countries in the Western Balkans and Türkiye as they prepare for full participation in ECDC's activities. This will enable them to fulfil ECDC requirements for data and information submission (including completeness and timeliness) at the minimum level required by the EU.

The focus of this stream is to:

- further enhance the communicable disease surveillance and control capacities of beneficiary countries;
- improve health emergency preparedness capabilities; and
- support the development of public health microbiology laboratory systems.

The expected results of this stream are:

- enhanced EU-level data so that communicable disease surveillance data are more comparable, timely and reliable when an IPA beneficiary joins the EU;
- long-term expansion of ECDC scientific and surveillance outputs, covering a broader geographical area within Europe that includes the Western Balkans and Türkiye; and
- improved response to public health threats from infectious diseases at the national level, with better early detection of and response to serious cross-border threats at the EU level.

In the context of Work Stream 1, ECDC conducted a technical visit to Montenegro to obtain additional information on the country's national surveillance system, including its operation and governance. The aim of this initiative was to provide ECDC with a comprehensive overview of the needs, vulnerabilities and strengths of the surveillance system. The insights gained from this visit will support the identification of opportunities for tailored support and areas where surveillance operations can be further strengthened.

Suggested citation: European Centre for Disease Prevention and Control. ECDC country visit to Montenegro to discuss surveillance of communicable diseases. Stockholm: ECDC; 2024.

Stockholm, March 2024

Background

The ECDC technical cooperation with the Western Balkans and Türkiye has enabled participating countries to report mutually agreed diseases to The European Surveillance System (TESSy) since 2016 (2015 data), attend ECDC meetings, network with colleagues and participate in some ECDC surveillance activities.

The Centre has incorporated capacity-building activities in the Western Balkans and Türkiye into the ECDC strategy 2021–2027and the Long-term surveillance framework 2021–2027.

In 2022, ECDC conducted an analysis of the quality of data reported to TESSy by the Western Balkans and Türkiye. Virtual bilateral meetings were then arranged with EU enlargement countries to discuss challenges and technical issues related to reporting, to identify needs for future ECDC support in strengthening national surveillance and to plan the next steps for joint surveillance activities.

National public health authorities in the Western Balkans and Türkiye have established or started to establish digitalised surveillance of notifiable diseases. They are also in the process of implementing the lessons learned from the COVID-19 pandemic.

However, the development of tailored capacity building in the Western Balkans and Türkiye, including the possible expansion of national routine reporting to TESSy for additional diseases, requires specific and detailed knowledge of how the national surveillance systems are organised.

Therefore, during bilateral meetings and a meeting with national correspondents and observer National Focal Points (NFPs) for Surveillance in November 2022, ECDC stressed the need for technical country visits to the Western Balkans and Türkiye as an immediate priority.

ECDC prepared an Assessment tool for national communicable disease surveillance systems to accompany the offer of a technical visit to Montenegro. The offer was accepted and the agenda for the visit was developed jointly with the Institute of Public Health (IPH) of Montenegro (Annex 2). During the visit, findings for all areas of surveillance were discussed and an assessment tool was filled out in collaboration with colleagues from Montenegro.

Purpose and objectives

The purpose of ECDC's technical visits to the Western Balkans and Türkiye is to identify areas in the surveillance of communicable diseases that may require further work, and possibly ECDC support. This will enable the countries to fulfil ECDC requirements for data and information submission, including completeness and timeliness, at the minimum level required by the EU. The visits also serve to meet the broader objectives of Work Stream 1, as set out above.

Specific objectives

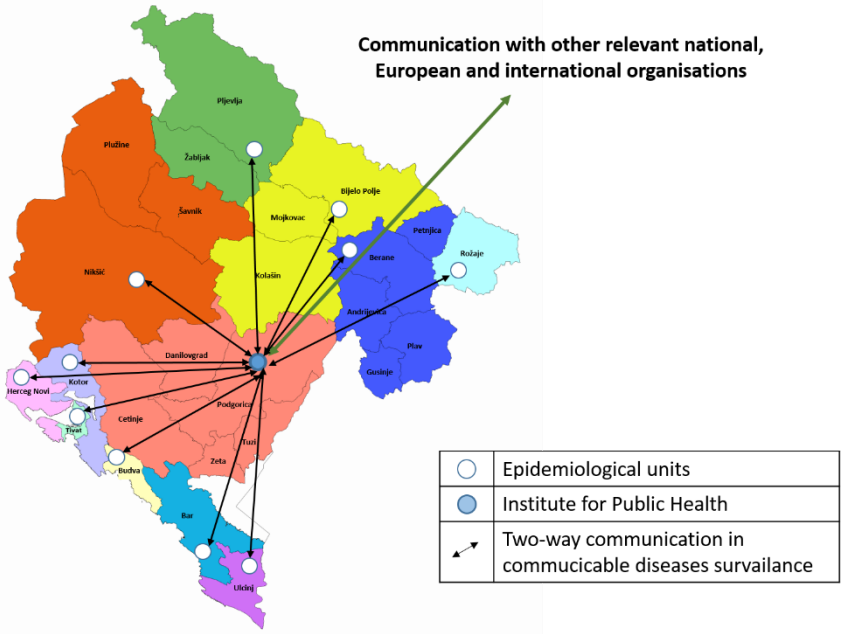
The specific objectives of technical visits to the Western Balkans and Türkiye are:

- to better understand the existing structures, systems, tools and processes involved in the national surveillance of communicable diseases, as well as any planned changes;
- to identify needs, vulnerabilities, strengths and areas for improvement related to the surveillance of communicable diseases, including aspects that might benefit from ECDC's technical support;
- to document the current situation concerning the strengths, vulnerabilities, needs and potential action plans; and
- to discuss and potentially agree on the next steps, as well as setting priorities for further surveillance activities that ECDC could support with technical guidance and assistance.

1. Surveillance system description

Montenegro's surveillance system for notifiable communicable diseases operates through a network of 11 epidemiological services and the Institute of Public Health of Montenegro (IPHMNE). The 11 epidemiological services are located at 11 of 18 Primary Health Centres (PHCs) in Montenegro (Figure 1). The IPHMNE coordinates all surveillance activities at the national level.

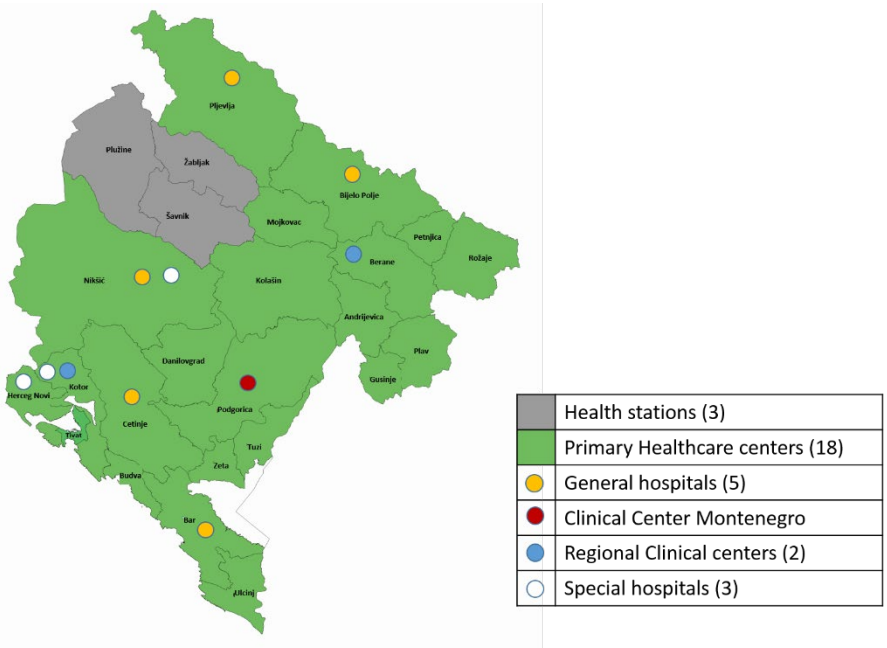
Figure 1. Geographical distribution of the 11 epidemiological services and the Institute of Public Health, Montenegro



Source: Institute of Public Health of Montenegro

The public healthcare system consists of 18 PHCs and three health stations which provide primary healthcare, five general hospitals providing secondary care, two regional clinical centres (Berane and Kotor) and the Clinical Centre of Montenegro in Podgorica which provide mainly tertiary care, and three special hospitals, including the Special Hospital for Tuberculosis (TB) at Brezovik (Figure 2).

Figure 2. Geographical distribution per administrative division of the type of healthcare facilities in the public health sector, Montenegro



Source: Institute of Public Health of Montenegro

The surveillance system covers 84 notifiable communicable diseases. Clinicians in primary, secondary and tertiary care from both public and private health sectors are required to notify these diseases to the responsible epidemiological service and to the IPHMNE at the same time. Medical doctors of all specialties in both the public and private sectors are required to report confirmed or suspected cases of communicable diseases under surveillance within 24 hours. Similarly, microbiologists must report the pathogens detected within 24 hours.

Montenegro has adopted a list of notifiable communicable diseases, based on the 'Commission Implementing Decision (EU)2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions'.

Explicit surveillance objectives have been developed for some diseases (e.g. measles, rubella, TB, HIV, influenza, COVID-19, severe acute respiratory infections (SARI) and HPV). These objectives have been shared with the relevant data providers.

The surveillance system is passive for most diseases (hospitals, clinics or physicians report their cases without being prompted by the IPH). Hospitals are asked to carry out active zero reporting (i.e. submitting reports even if there are no cases) on a weekly basis for acute flaccid paralysis (AFP), and monthly for measles, rubella and congenital rubella syndrome.

There is a sentinel surveillance system for influenza-like illness (ILI), acute respiratory infections (ARI) and SARI. For ILI/ARI, there are two systems: one is year-round population surveillance with electronic reporting from all PHCs in the country, and the other is sentinel surveillance during the flu season (from week 40 to week 20 of the following year). The latter operates at two PHCs in Podgoritsa (the PHC in Berane, and the PHC in Ulcini), also with electronic reporting. There are three sentinel sites for SARI: the General Hospital in Berane, the Special Hospital for Pulmonary Diseases on TB in Brezovik, and the Clinical Centre of Montenegro, all with electronic reporting.

There is a syndromic surveillance system for AFP, measles, rubella, and congenital rubella syndrome (CRS). In the event that the syndromic surveillance system detects one of the above-mentioned diseases or syndromes, the law stipulates that an 'urgent reaction' or 'urgent notification' should be triggered.

An urgent reaction or urgent notification is also required when there is suspicion or confirmation of a case of cholera, plague, yellow fever, viral haemorrhagic fever (except haemorrhagic fever with renal syndrome), poliomyelitis, diphtheria, smallpox, measles, botulism, SARS (regardless of the cause), influenza caused by new influenza virus subtypes, the risk of a biological agent having been used, or the suspicion that an agent may have been used. Urgent measures are also implemented if there is a suspicion of an infectious disease epidemic.

In addition, Event-Based Surveillance (EBS) is conducted at both national and local level, using information from the media, social networks, community sources, healthcare institutions, the veterinary sector, and official notification channels (WHO, ECDC, ELDSNet).

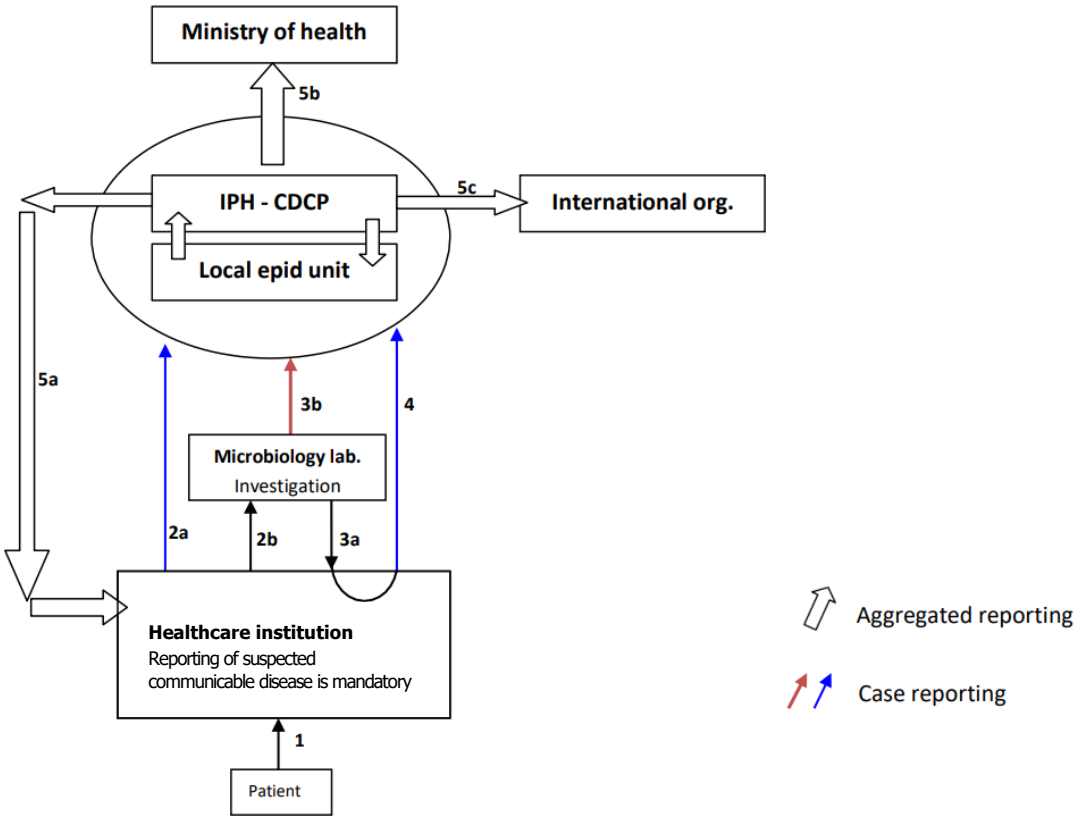
All events designated as urgent are immediately assessed in terms of risk (epidemiological services have 24-hour standby duty).

There are established procedures for the evaluation of the surveillance system. There was an internal evaluation for SARI in 2019 and for measles, rubella, CRS and AFP in 2022. In addition, there was a joint external evaluation of Montenegro's IHR core capacities, including surveillance, in 2019.

2. Data collection

Notifiable communicable disease cases (suspected or confirmed) and pathogens must be reported to the IPHMNE and the relevant/responsible epidemiological service by medical doctors and microbiologists (Figure 3).

Figure 3. Data flow for a confirmed or suspected case of a communicable disease, Montenegro, 2023



Source: Institute of Public Health of Montenegro

Data collection relies on both an electronic-based reporting system (intranet) with a central database through a specific system (integrated information health system) at the national level, and a paper-based reporting system with a central computerised database, also at the national level.

There is no link between clinical and laboratory reporting. These are two different reporting systems.

Electronic reporting is carried out by medical doctors from PHCs, and special and general hospitals. At present, the Clinical Centre of Montenegro and the private healthcare sector are not included in the electronic reporting system. They report through a paper case notification form to both epidemiological services and the IPHMNE. IPHMNE staff then manually enter data from these paper forms into the electronic database. The electronic reporting system allows for the registration of additional information collected during the epidemiological investigations.

In addition, epidemiologists from the IPHMNE visit the Clinical Centre of Montenegro on a daily basis, looking for cases with notifiable communicable diseases that have not yet been reported to the IPHMNE. Case classification is included in the case reporting form by clinicians.

With regard to laboratory reporting, if a notifiable communicable disease agent is isolated in a laboratory, the microbiologist at the laboratory must report it using a paper case notification form.

Results must be communicated to:

- the healthcare institution that ordered the laboratory testing, and
- the IPHMNE and the relevant/responsible epidemiological service.

In addition, laboratories must also notify the Administration of Inspection Affairs (AIA), and the Directorate responsible for Food Safety, Veterinary and Phytosanitary Affairs (DFSVMPA) for zoonosis and food-borne diseases.

There is a rulebook on the reporting of communicable diseases, hospital inspections, and conditions and mortality caused by these diseases (OG MN, No. 023/20 041/20). The rulebook on reporting provides guidance and instruction on the procedures to be followed when reporting notifiable communicable diseases.

There are several types of paper reporting forms, as follows:

- Notifiable communicable diseases form used by medical doctors (same for all notifiable diseases except for HIV, TB and hepatitis B and C, and laboratory-confirmed cases of influenza and malaria);
- Laboratory reporting form used by microbiologists (same for all notifiable diseases);
- Case investigation form for some communicable diseases or groups of diseases, used by epidemiologists. This form enables additional information to be collected during outbreak investigations or to comply with TESSy requirements;
- Reporting form for injury involving animals/risk of contact through animals;
- Reporting form for healthcare-associated infection;
- Sentinel hospital SARI survailance reporting form;
- Outbreak reporting form.

The data collected for each communicable disease are case-based except for ILI/ARI, where they are aggregated, and for SARI and COVID-19 data, where they are both aggregated and case-based.

3. Data quality

Validation of routine surveillance data is partly automated and partly manual at the national level. For example, variable coding errors and duplicates are checked automatically, while logical links between case data are checked manually.

Completeness is routinely monitored for all communicable notifiable diseases, whereas timeliness is routinely monitored only for vaccine preventable diseases (VPD). There is no systematic monitoring of surveillance data quality.

4. Data management

Data are entered into the electronic reporting system by medical doctors. Exceptions to this rule are cases of notifiable communicable diseases that are reported using the paper-based form (from private healthcare facilities and the Clinical Center of Montenegro) and those entered into the electronic system by IPHMNE staff.

There are two main datasets at the IPHMNE containing information on notifiable communicable diseases:

- database in Oracle: includes the clinical data from medical doctors through both the electronic and paper-based reporting systems. Paper-based forms for communicable diseases sent by medical doctors are manually entered by IPHMNE staff;
- data in Microsoft Excel: laboratory data from the paper-based reporting system are entered into Excel by the IPHMNE staff, except for the data for COVID-19 which are already in Excel format.

There is no merged dataset that includes clinical and laboratory data for reported cases of notifiable communicable diseases. However, it is possible (where applicable) to link clinical and laboratory data.

The surveillance data protection is compliant with the EU regulation for data protection which has adopted into national law by Montenegro.

Cases of notifiable diseases are reported using the unique ID number of Montenegrin citizens. All government organisations use the National Health Insurance Fund which contains the ID numbers of citizens.

For HIV, all cases are reported to IPHMNE with personal data, including the unique citizen ID number. Access to the register is limited and only nominated IPHMNE staff have access to the data, including the names of the cases.

5. Data analysis

Routine descriptive analyses of the surveillance data are performed weekly, monthly and annually, including trend monitoring for all notifiable communicable diseases. These analyses are carried out at both district and national levels and are semi-automated, as templates for illustrations and indicator measurements have been developed in Excel databases.

Exceptions for the analysis frequency are the annual analysis of HIV cases, weekly analysis of COVID-19 cases, and weekly analysis of influenza cases during the influenza season.

National disease rates are not routinely compared to EU/EEA rates. Comparisons are only made when a scientific paper is developed by IPHMNE or in the event of an increase in cases of a certain communicable disease.

The weekly, monthly and annual reports include recommendations if the data analysis indicates the need for further action at district or national level (e.g. an increase in cases of a communicable disease).

Risk factor studies are conducted for HIV (biological-behavioural surveys among sex workers, men who have sex with men, People Who Inject Drugs (PWID), and prisoners), and sometimes during outbreak investigations (e.g. food- and water-borne disease outbreaks).

6. Dissemination of communicable disease surveillance data

The IPHMNE produces weekly, monthly and annual epidemiological reports for the communicable diseases notified.

Weekly reports include the number of notifiable disease cases reported during the previous week at national and district levels. Monthly and annual reports include the number of cases and rates per 100 000 population for each disease.

The reports are available online on the IPHMNE website. They are also disseminated to public health professionals, primary healthcare institutions, general hospitals, the Ministry of Health, the Food Safety and Veterinary Agency, and the Directorate for Sanitary Inspections.

In addition, there is a dashboard with COVID-19 cases on the IPHMNE website (https://www.ijzcg.me/). There are also automated outputs for Measles-Mumps-Rubella (MMR) and Human Papillomavirus (HPV) vaccine coverage.

7. Outbreak detection

The Indicator-Based Surveillance (IBS) system, the syndromic surveillance system, and the Event-Based Surveillance system (EBS) are used to detect outbreaks.

The definition and criteria for determining an outbreak have been established (for a few diseases), along with a regulation covering the reporting of outbreaks.

The most recent outbreaks detected through the IBS system (in 2022) included one pharyngitis acute streptococcal outbreak and two hepatitis A outbreaks which were probably linked.

In the first hepatitis A outbreak, 20 cases were reported between 1 September and 6 October 2022, and 16 (80%) were hospitalised. All cases came from the same municipality, a coastal region with high levels of tourism. The IPMNE was informed of the outbreak on 14 September 2022, although the source of infection remains unknown.

With regard to the second hepatitis A outbreak, the signal was detected on 8 September 2022, but it seems that there had been cases with hepatitis-A-compatible symptoms since mid-July 2022.

Most cases were linked to a restaurant, either as employees or as customers. The restaurant was in a coastal municipality bordering the area where the first hepatitis A outbreak occurred.

Following an extensive investigation, it was determined that all 30 restaurant employees had been exposed (the attack rate was around 30% among those employed), along with any customers (unknown number) who visited the restaurant from the middle of July to 6 October 2023.

The two outbreaks appreared to be linked since three cases of hepatitis A were recorded among the employees at a hotel in the municipality where the first epidemic occurred, which was supplied with catering from the restaurant in the municipality where the second epidemic occurred.

The total number of cases was 10, and nine were hospitalised. The source of the infection remains unknown.

8. Capacity

There is laboratory capacity to diagnose the majority of the 84 notifiable communicable diseases.

There is no laboratorycapacity for confirmation of suspected cases of anthrax, botulism, Variant Creutzfeldt-Jakob disease, plague, poliomyelitis, rabies, STEC/VTEC, smallpox, tularaemia, viral haemorrhagic fevers (except hantavirus infection), yellow fever, Zika virus disease, congenital Zika virus infection, and MERS-CoV.

For any suspected case of poliomyelitis, the sample is sent to Serbia (Torlak Institute). For any PCR-confirmed case of measles or rubella, the sample is sent to the WHO Collaborating Centre for Measles Infections in Luxembourg for genotyping. PCR-confirmed cases of influenza, are sent to the WHO Collaborating Centre for Influenza in London for subtyping (including sequences and sensitivity to antiviral drugs).

Montenegro has capacity for molecular surveillance of COVID-19.

With regard to the training of healthcare professionals on communicable disease case reporting, there is periodic training for new staff and when there is an update in the surveillance system related to reporting.

In 2023, there were approximately 35 epidemiologists (specialising in communicable diseases) working in the public health system. In addition, the workforce includes approximately 15 medical technicians who are responsible for the administrative work, including data entry.

9. Conclusions and recommendations

During this ECDC technical visit, it was observed that Montenegro is continuing to make improvements in the area of surveillance. However, some systemic challenges remained. Based on the assessment, ECDC recommends that Montenegro should:

- Review and possibly update surveillance objectives;
- Establish a link between clinical and laboratory data reporting forms/data;
- Explore the possibility of including the Clinical Centre of Montenegro and the private healthcare sector in the electronic-based surveillance reporting system;
- Consider automating:
  - the monitoring of data quality indicators,
  - the production of routine outputs, and
  - the signal detection;
- Pilot the use of tools to detect signals for outbreaks (e.g. the EpiSignalDetection tool);
- Explore the possibility of advanced analysis of the surveillance data, (e.g. more risk factor analyses);
- Strengthen laboratory capacity for priority pathogens to support the surveillance system and consider increasing sequencing and molecular epidemiology capacity;
- Strengthen cooperation with private healthcare providers for the purposes of surveillance (e.g. diagnosis of cases, reporting, etc.)

ECDC could provide support for some of these activities, including:

- Training in the preparation of surveillance outputs, including running R scripts or mapping with ECDC's Map Maker tool (EMMa);
- Training in data management to help automate data cleaning and quality checks;
- Support for the implementation of data quality indicators.

Annex 1. Country visit teams

ECDC team

- Julien Beauté (ECDC Team Leader), Principal Expert General Surveillance, Public Health Functions Unit.
- Adrian Prodan, Surveillance Platform User Support Manager, Public Health Functions Unit (joined remotely for the training on TESSy session).
- Maria Tseroni, external EU Member State expert surveillance, Greece.

Country team – Institute of Public Health of Montenegro

- Dr Nebojša Sekulić, Epidemiologist, Director of Centre for Communicable Disease Control and Prevention, ECDC Observer NFP for Emerging Viral Diseases.
- Dr Sanja Medenica, Epidemiologist, Centre for Science.
- Dr Božidarka Rakočević, Epidemiologist, Centre for Disease Control and Prevention, Observer NFP for Threat Detection, Observer NFP for Viral Respiratory Diseases
- Dr Maja Milanovic, Centre for Communicable Disease Control and Prevention Department, Centre for Disease Control and Prevention, ECDC Observer NFP for Preparedness and Response
- Dr Danijela Rajković, Specialist in Microbiology, ECDC Observer NFP for Microbiology, Contact Point for Operations Microbiology for Emerging Viral Diseases.
- Dr Adis Martinović, Head of Department for Immunisation, Centre for Communicable Disease Control and Prevention.
- Dr Marjan Bakić, Head of Department, Centre for Communicable Disease Control and Prevention.
- Mr Ana Radulović, Mathematician.
- Branko Dujović, Software engineer.
- Alexandra Marianović, Specialist in Social Medicine, Counselling Centre for HIV.

Annex 2. Agenda

Day 0 - 12 September 2023	
Arrival	Boscovich Boutique Hotel, Marka Miljanova, Podgorica

Day 1 - 13 September 2023 Institute of Public Health of Montenegro, Dzona Dzeksona bb, Podgorica, Room 12		
Time	**Topic**	**Participants**
09:00–09:30	Welcome and introduction to the meeting	Dr Nebojša Sekulić
09:30–10:00	Surveillance of infectious diseases at EU/EEA level and strengthening surveillance in Western Balkans (presentation approximately 30 mins)	Julien Beauté, ECDC
10:00–10:15	Break	
10:15–12:00	Description of infectious disease surveillance system in Montenegro (presentation approximately 30 mins) Discussion (approximately 1 hour)	Dr Sanja Medenica Montenegro IPH team, ECDC
12:00–13:00	Lunch break	
13:00–14:00	Data collection	Montenegro IPH team, ECDC
14:00–15:00	Data quality	Montenegro IPH team, ECDC
15:00–16:00	Data management	Montenegro IPH team, ECDC

Day 2, 14 September 2023 Institute of Public Health of Montenegro, Dzona Dzeksona bb, Podgorica, Room 12		
Time	**Topic**	**Participants**
09:00–09.30	Wrap-up of the first day	Julien Beauté, ECDC
09:30–12:30	Data analysis	Montenegro IPH team, ECDC
	Dissemination of the communicable disease surveillance data	
	Break	
	Outbreak detection	
	Capacity	
12:30–13:30	Lunch break	
13:30–14:00	Discussion on selected diseases reported to ECDC	Montenegro IPH team, ECDC
14:30–16:00	Training on TESSy reporting in the context of new EpiPulse portal. Short presentation for TESSY reporting for mandatory diseases for new staff.	Adrian Prodan, ECDC
16:00–17:00	Debriefing session: Draft conclusions and way forward.	ECDC, Montenegro IPH team Representative from EU Delegation

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