

ECDC accession support to the Western Balkans and Türkiye

ECDC country visit to North Macedonia to discuss surveillance of communicable diseases

May 2023

Introduction

ECDC is helping countries in the Western Balkans and Türkiye improve their infectious disease prevention and control systems and public health workforce. This will prepare the countries 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).

Implementation of this Action is structured around three technical Work Streams. 'Work Stream 1: Preparatory measures to enable the authorities of IPA beneficiaries to participate in ECDC activities and systems' aims 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 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:

- better EU-level data so that communicable disease surveillance data are more comparable, timely and reliable when an IPA beneficiary joins the EU or ECDC;
- more comprehensive ECDC scientific and surveillance outputs in the long term, 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 North Macedonia to acquire additional knowledge and information on the country's national surveillance system, as well as how the system is operated and governed. These insights will provide ECDC with a comprehensive overview of the needs, vulnerabilities and strengths of the surveillance system and support identification of opportunities for tailored support and areas where surveillance operations can be further strengthened.

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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.

ECDC has incorporated capacity-building activities in the Western Balkans and Türkiye in the [ECDC strategy 2021–2027](#) and in the [Long-term surveillance framework 2021–2027](#).

In 2022, ECDC conducted an analysis of the quality of the data reported to TESSy by the Western Balkans and Türkiye. Subsequently, virtual bilateral meetings with EU enlargement countries took place 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, developing tailored capacity building in the Western Balkans and Türkiye, including the possible expansion of national routine reporting to TESSy for additional diseases, requires ECDC to obtain specific and detailed knowledge of how the national surveillance systems are organised.

Therefore, during bilateral meetings and a meeting with National ECDC Correspondents and observer National Focal Points (NFPs) for Surveillance in November 2022, ECDC stressed the need for technical country visits in 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 North Macedonia. The offer was accepted and the agenda for the visit was developed jointly with the Institute of Public Health (IPH) of North Macedonia (Annex). Findings for all areas of surveillance were discussed during the visit and an assessment tool was filled out in collaboration with North Macedonian colleagues.

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 where further work (and possibly ECDC support) would be required to enable them to fulfil ECDC requirements for data and information submission (including completeness and timeliness) at the minimum level required by the EU. They also serve to meet the broader WS1 objectives.

Specific objectives

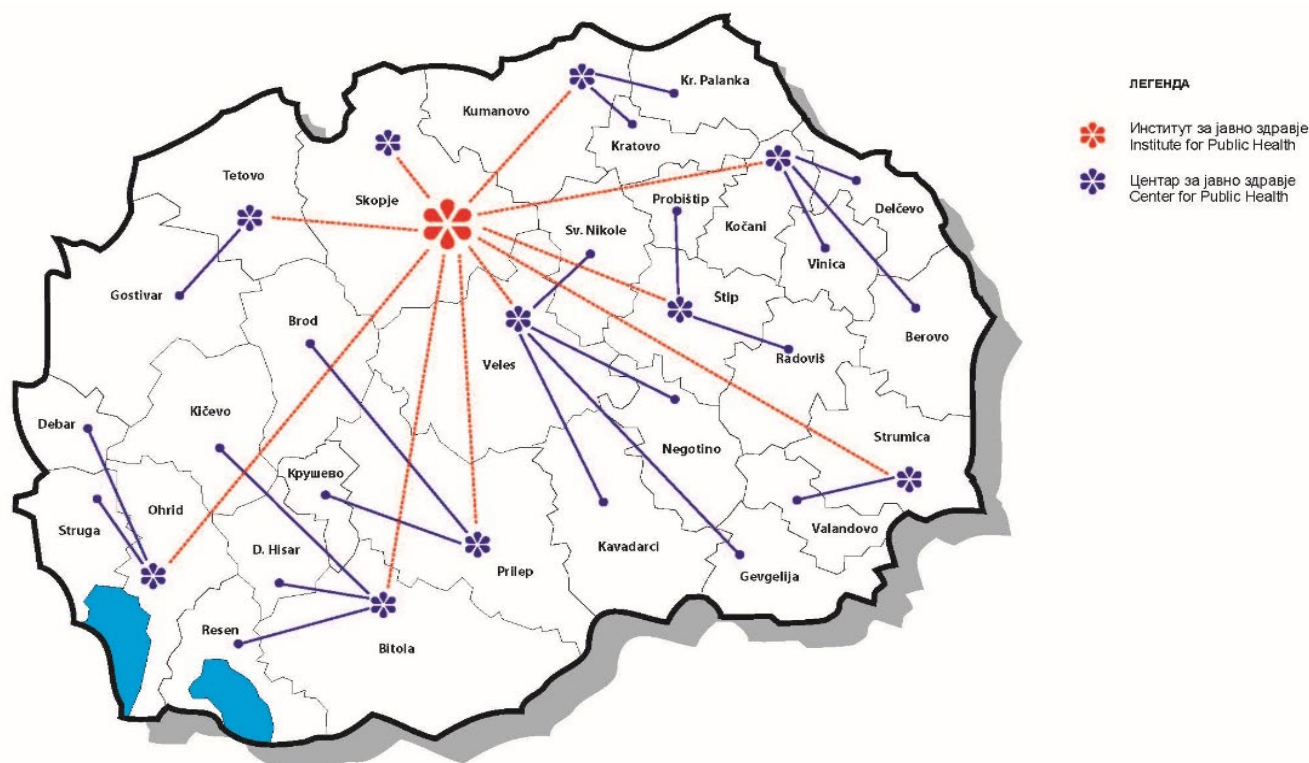
The specific objectives of technical visits to the Western Balkans and Türkiye are:

- 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 relating to the surveillance of communicable diseases, including aspects that might benefit from ECDC's technical support;
- to document the current situation around these strengths, vulnerabilities, needs and potential plans of action; and
- to discuss and potentially agree on the next steps, as well as set priorities for further surveillance activities that ECDC could support with technical guidance and assistance.

1 Surveillance system description

North Macedonia's surveillance system for notifiable diseases operates through an established network of 21 Units of the Centres of Public Health (UCPH) at the local level and 10 Centres of Public Health (CPH) at the regional level. The Institute of Public Health (IPH) in Skopje coordinates all surveillance activities at the national level (Figure 1).

Figure 1. Geographical distribution of Units of the Centres of Public Health, Centres of Public Health and the Institute of Public Health, North Macedonia



Source: Institute of Public Health of the Republic of North Macedonia

The surveillance system covers 64 communicable diseases and 56 pathogens. Primary, secondary and tertiary care clinicians from the public and private health sectors are required to notify these diseases to the relevant public health authorities. Medical doctors (all specialities) from the public and private sectors are obligated to report confirmed or suspected cases of communicable diseases under surveillance within 24 hours. Similarly, microbiologists must report the detected pathogens within 24–48 hours.

An updated 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' is expected to be adopted in a new law.

Explicit surveillance objectives have been developed for some diseases, either individually or as groups of diseases (e.g. smallpox, rubella, influenza, influenza-like illness, severe acute respiratory infections (SARI), measles and acute flaccid paralysis (AFP)). The objectives for measles, rubella, influenza, influenza-like illness, SARI and AFP have been shared with hospitals and the Centres for Public Health at the regional level.

The surveillance system is passive for all diseases except AFP, measles and rubella, where active zero reporting by hospitals is requested every week. There is subnational sentinel surveillance for SARI, including six hospitals from two regions of North Macedonia.

In addition, there are two syndromic surveillance systems in place. The ALERT (EWARN) surveillance system, introduced in 2005, includes eight syndromes but provides results (alerts) with a delay of one week. The ALERT.2 surveillance system operates in real-time using ICD-10 codes from the electronic health records and includes nine defined groups of diseases. The legal framework for this system is pending. When the ALERT. 2 surveillance system is adopted by law, the ALERT (EWARN) surveillance system will cease to operate.

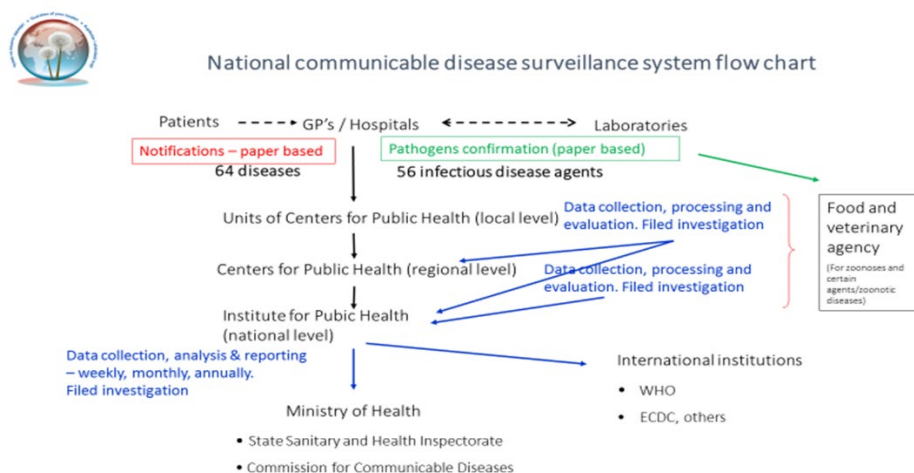
There are no established procedures for the evaluation of any of the above systems. There was an internal evaluation of the sentinel surveillance system for SARI for the 2015/2016 influenza season by a MediPIET fellow.

2 Data collection

Data collection relies on a paper-based system, with a central computerised database at the national level. There is a separate web-based reporting system for COVID-19.

Notifiable communicable disease cases (suspected or confirmed) and pathogens must be reported to the UCPH on specific forms by medical doctors and microbiologists, respectively. Epidemiologists at the local level implement the case (field) investigations and send the notification forms to the CPH, where epidemiologists perform data entry, analyse the data in their own database, do further case investigations (if needed) and send copies of the forms to the IPH. At the IPH, technical staff enter case data again and epidemiologists analyse the data to prepare weekly, monthly and annual reports (Figure 2).

Figure 2. Data flow for a confirmed or suspected case of a communicable disease, North Macedonia, 2023



Source: Institute of Public Health of the Republic of North Macedonia

Data entry at both the regional level and the national level means duplication of work. In addition, sometimes there is a delay in sending the forms from the regional level to the national level.

A web-based reporting system modelled after the system currently being used for COVID-19 is being developed for all notifiable diseases.

North Macedonia has adopted the case definitions for surveillance of notifiable diseases according to the '2012/506/EU: Commission Implementing Decision of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council', but they are not used. Generally, the cases are not classified as confirmed, probable or possible.

Harmonising with the Decision 2018/945/EC case definitions is in progress, but the 2018 EU case definitions are used when reporting to TESSy.

There are three types of reporting forms, as follows:

- Notifiable diseases form used by medical doctors (same for all notifiable diseases)
- Laboratory reporting form used by microbiologists (same for all notifiable diseases)
- Case (field) investigation form used by epidemiologists (disease specific)

There are standard operating procedures for reporting HIV, malaria, measles, rubella, influenza, COVID-19, AFP and brucellosis. There is also a '[Rulebook on the method of reporting and the form and content of the forms for reporting infectious and microbiologically proven diseases](#)' (edition 2009), but it is outdated.

The collected data for each communicable disease are case based. Seasonal influenza (from week 40 to week 20 the following year) data are aggregated and SARI data are both aggregated and case based. Out of season, influenza data are case based.

3 Data quality

Validation of routine surveillance data is performed manually (e.g. variable coding errors, duplicates and logical links between case data). Automated validation exists only for COVID-19 data. Other data quality attributes are not routinely monitored (e.g. completeness, timeliness, etc.).

4 Data management

There are two main datasets in Microsoft Excel format that contain information on:

- Lab pathogens: data from the reporting forms coming from laboratories
- Communicable diseases: data from the case reporting forms coming from medical doctors (This database includes all notifiable diseases except COVID-19.)

In addition, there are separate Excel datasets for the following diseases:

- Measles and rubella
- Brucellosis
- SARI (There are two datasets, one case based and one aggregated, creating redundancy as they need to be checked against each other for discrepancies.)
- HIV

The data reported to TESSy contain information from the laboratories merged with epidemiological information extracted from the paper-based case investigation forms from the epidemiologists, not from the case reporting forms from medical doctors that are centralised in the Excel datasets. The data from case investigation forms are not stored in the Excel datasets.

Data on COVID-19 are stored in an electronic database based on PostgreSQL with a Java front end. Epidemiologists and other staff enter the epidemiological investigation data into a predefined form based on the World Health Organization (WHO) case investigation form. The data are validated and cleaned in the electronic system and are analysed using Excel.

North Macedonia has not implemented the provisions of the EU General Data Protection Regulation (GDPR). For HIV cases, the data are pseudonymised.

Personally identifiable information, including names and national identification numbers, are collected and used to identify cases. For HIV, the names and national ID numbers are replaced by an HIV-specific ID that contains name initials, the year and the case counter.

5 Data analysis

Routine descriptive analysis of the surveillance data (monthly and annually) is performed to calculate disease rates. The analysis is performed at the regional and national levels and is semi-automated, as pivot tables have been developed in the Excel databases.

The national disease rates are not compared to EU/EEA rates except for influenza, COVID-19, measles (including immunisation rates) and specific diseases in the event of an outbreak.

The monthly and annual reports do not include recommendations for further actions. However, if the data analysis indicates the need for further action at the regional or national levels, the IPH communicates this (verbally or in writing) to the regional epidemiologists or the Committee for Infectious Diseases of the Ministry of Health.

6 Dissemination of communicable disease surveillance data

The IPH produces weekly, monthly and annual epidemiological reports for the reported communicable diseases.

The weekly report includes the number of notifiable disease cases reported the previous week at national and subnational levels. Seasonal influenza and COVID-19 weekly reports include an analysis of the data.

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 IPH website and they are also disseminated to local and regional public health professionals, the Ministry of Health, the Committee for Infectious Diseases of the Ministry of Health, the State Sanitary and Health Inspectorate, the Food and Veterinary Agency, the Medical Faculty, the Army Medical Centre and the Centre for Crisis Management.

7 Outbreak detection

The Indicator Based Surveillance (IBS) system and the syndromic surveillance systems are used to detect outbreaks. Both syndromic surveillance systems have automated signal detection.

The latest outbreaks detected through the IBS system include a measles outbreak in 2018 and 2019, as well as several small Hepatitis A outbreaks in 2019.

Definition and criteria to determine an outbreak have been established in the 'Law on the Protection of the Population from Infectious Diseases' (Official Gazette of the Republic of Macedonia No. 66/2004). Additional guidelines exist in the national Rulebook, in standard operating procedures in an Emergency Operation Centre Handbook and in 20 standard operating procedures stored on a OneDrive that is accessible to all epidemiologists.

8 Capacity

North Macedonia has capacity for molecular surveillance of COVID-19 and influenza (SARI samples). In addition, there is a collaboration with the Regional WHO Laboratory in Luxembourg for molecular analysis of measles and rubella cases.

There is laboratory capacity to diagnose most of the 64 notifiable communicable diseases. There is no laboratory capacity for confirmation of suspected cases of anthrax, diphtheria, Ebola, Marburg haemorrhagic fever or polio.

For any suspected case of Ebola, the sample is sent to the Charité Hospital in Berlin. For any suspected case of polio, the sample is sent to a laboratory in Sofia, Bulgaria. If the result is positive, the sample is then forwarded to a laboratory in Italy for confirmation. There is an official agreement with the laboratory in Sofia. Samples are sent to the National Institute for Public Health and the Environment (RIVM) in Utrecht for confirmation of cases of other communicable diseases.

The only regular training programme for healthcare professionals on communicable disease case reporting is for SARI. For the SARI sentinel surveillance system, there is an established annual training for healthcare professionals.

In total, 37 epidemiologists (29 fully qualified and 8 in specialty training) work in the public health system in 2023. However, the total number of epidemiologists working in public health has decreased from 46 in 2016. The workforce also includes 50 data managers who are responsible for data entry. Data managers are mostly technicians with three years of university-level studies (usually in health science training, statistics or lab technician studies), and not all of them have specific computer training.

There is no dedicated administrative and IT support for the IPH, but the Ministry of Health provides limited administrative support and IT maintenance.

9 Conclusions and recommendations

During this ECDC technical visit it was observed that North Macedonia continues to make improvements in the area of surveillance. However, several systemic challenges remain. According to the assessment, ECDC recommends that North Macedonia should:

- Review and possibly update surveillance objectives.
- Harmonise the list of notifiable diseases and case definitions with Decision 2018/945/EC.
- Simplify data entry at the regional and national levels.
- Ensure integration of clinical and laboratory reporting forms, and integrate data entry of epidemiological investigation forms into the current system.
- Consider implementing classification of cases in the current system, according to EU case definitions.
- Conduct studies to assess possible under-ascertainment of cases.
- Consider more analyses of the surveillance data, taking advantage of unique identifiers for advanced analyses, including:
 - expanding trend analyses to additional diseases, especially for diseases for which increasing trends were reported in Europe (e.g. Legionnaires' disease), and
 - conducting more risk factor analyses, for example for poor outcome (e.g. tuberculosis) or late diagnosis (e.g. HIV).
- Launch the web-based reporting system for all notifiable diseases as soon as possible. This system should link the case report form, laboratory report form and investigation form, and should include the classification of the case.

- Monitor data quality and automate additional data quality checks (e.g. missing values, timeliness, etc.).
- Consider automating the production of routine outputs.
- Provide feedback to data providers (e.g. adding data quality indicators in surveillance reports).
- Explore the possibility of preparing other outputs for target audiences, such as vaccine-preventable disease reports for the public to improve vaccine uptake.
- Strengthen laboratory capacity for priority pathogens to support the surveillance system and consider increasing sequencing and molecular epidemiology capacity.
- Pilot the use of tools to detect signals for outbreaks (e.g. the [EpiSignalDetection tool](#)).
- Strengthen training, incentives and career opportunities to increase public health human resource capacity (e.g. providing motivation to medical doctors and veterinarians to choose epidemiology and training other health professionals (e.g. biologists, health visitors, nurses, bioinformaticians, etc.) in epidemiology).
- Strengthen cooperation with private healthcare providers for the purpose of surveillance (e.g. diagnosis of cases, reporting, etc.).

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

- Providing training in the preparation of surveillance outputs, including running [R scripts](#) or mapping with the [ECDC Map Maker tool \(EMMa\)](#).
- Providing training in data management to help automate data cleaning and quality checks.
- Providing training in disease prioritisation using the [ECDC tool for the prioritisation of infectious disease threats](#).

Annex

Agenda

ECDC team:

- Julien Beauté (Team Leader), Principal Expert General Surveillance, Public Health Functions Unit
- Maria Tseroni, Project Scientific Officer Surveillance and Data, Public Health Functions Unit
- Adrian Prodan, Surveillance Platform User Support Manager, Public Health Functions Unit
- Agnè Bajorinienè, International Relations Officer, European and International Cooperation Section, Director's Office

Country team:

- Zharko Karadzovski, Head of the Unit for prevention and control of communicable diseases
- Kristina Stavridis, Head of the Unit for immunization and VPD
- Dragan Kocinski, Epidemiologist
- Enkela Polozhani, MD

Tuesday, 2 May 2023		
Arrival	Hotel IBIS SKOPJE CITY CENTER, Orce Nikolov Br 55, Skopje	
Wednesday, 3 May 2023		
Emergency Operation Centre (EOC) premises		
Time	Topic	Participants from IPH of North Macedonia and ECDC
9:00–9:30	ECDC team meeting with the Director of the Institute of Public Health (IPH)	Doc Dr. Shaban Memeti
9:30–9:45	Welcome and introduction to the meeting (EOC)	Dr. Zharko Karadzovski
9:45–10:15	Surveillance of infectious diseases at EU/EEA level and strengthening surveillance in Western Balkans	Julien Beaute, ECDC
10.15–12:00	Description of infectious disease surveillance system in North Macedonia (approximately 30 mins) Discussion	Dr. Dragan Kochinski IPH epi team, ECDC
12.00–12.30	Break	
12.30–13.30	Data collection	IPH epi team, ECDC
13.15–14.30	Data quality	IPH epi team, ECDC
14.30–15.30	Data management	IPH epi team, ECDC
15.30–16.30	Lunch	
Thursday, 4 May 2023		
Time	Topic	Participants from IPH
9:00–9:30	Wrap-up of the first day	ECDC team
9.30–12.30	<ul style="list-style-type: none"> • Data analysis • Dissemination of the communicable disease surveillance data • Outbreak detection 	IPH epi team, ECDC
12.30–13.00	Break	
13.00–14.00	Discussion on selected diseases reported to ECDC	IPH epi team, ECDC
14.00–15.30	TESSy reporting training (epi and lab staff) Basics of TESSy reporting for new IPH epi and lab staff Reporting of existing diseases, Q&A Additional topics, Q&A	ECDC Radica Stolevska Ilioska Zivadinka Cvetanovska Mirvete Ismani Dina Chibisheva Amra Fejzula Esra Bilali Natasa Kolevska Zekirija Alili Teodora Buzarova Gordana Nikolovska
15.30–16.00	Debriefing session: Draft conclusions and way forward	ECDC, IPH epi team
16.00–17.00	Lunch	

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