

CAPACITY/CAPABILITY ASSESSMENT

ECDC country visit to Serbia to discuss surveillance of communicable diseases

ECDC Accession Support to Western Balkans and Türkiye 2025

Introduction

ECDC cooperates with countries in the Western Balkans and Türkiye to improve their infectious disease prevention and control systems and public health workforce to prepare them for their future participation in ECDC's work.

Technical cooperation with countries in the Western Balkans and Türkiye [1] aims, in particular, to support capacities to implement EU rules on communicable diseases, improve the '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's European Neighbourhood Policy and Enlargement Negotiations (DG NEAR) [2] under the Instrument of Pre-accession Assistance (IPA) [3].

The project is structured around three technical work streams. Work Stream 1 encompasses preparatory measures to enable IPA beneficiaries to enhance communicable disease surveillance and control capacities, improve health emergency preparedness and support public health laboratory systems development [1]. This will enable the national health authorities to fulfil ECDC's requirements for disease data submission at the minimum level required by the EU. The expected results of this stream are, therefore:

- enhanced EU-level data so that communicable disease surveillance data are more comparable, timely and reliable;
- long-term expansion of ECDC's 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 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 Serbia in April 2024 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. To help ECDC ensure the consistency of the visit and follow-up of progress, an assessment tool was used [4]. The tool included eight topics regarded as core areas for successful communicable disease surveillance and control and was used as guide for discussion. The insights gained within the assessment mission were used for the identification of areas where surveillance operations could be further strengthened and aspects that ought to benefit from ECDC's technical support or guidance.

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Background

ECDC's 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 2021–2027](#) and the [long-term surveillance framework 2021–2027](#).

In 2022, ECDC analysed 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, identify needs for future ECDC support in strengthening national surveillance and plan the next steps for joint surveillance activities.

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

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

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

ECDC prepared an [Assessment tool for national communicable disease surveillance systems](#) to accompany the offer of a technical visit to Serbia. The offer was accepted and the agenda for the visit was developed jointly with the Institute of Public Health of Serbia 'Dr Milan Jovanovic Batut' (IPHS). During the visit, findings for all areas of surveillance were discussed and an assessment tool was filled out in collaboration with colleagues from the country.

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 possible 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;
- to discuss and potentially agree upon next steps, as well as setting priorities for further surveillance activities that ECDC could support with technical guidance and assistance.

1. Surveillance system description

Communicable disease surveillance in Serbia is coordinated with veterinary surveillance and blood and tissue product safety so that whenever needed information can also be exchanged with non-communicable disease surveillance. The list of notifiable diseases is regulated by the Law on the Protection of the Population against Communicable Diseases [5-7].

For certain diseases, there are methodological surveillance guidelines. For most diseases, surveillance is primarily passive, but active surveillance is conducted for some (e.g. measles, rubella and congenital rubella syndrome, acute flaccid paralysis) [8]. Emerging diseases, such as viral hepatitis of unknown origin among children aged less than 16 years, can be included in surveillance schemes without need to change the current legislation.

Most communicable diseases under surveillance have a comprehensive surveillance scheme, in which all territory is included, and both private and public sector are mandated to report notifiable communicable diseases, at all levels of healthcare (primary, secondary and tertiary).

Sentinel surveillance of influenza-like illness (ILI), acute respiratory infection (ARI) and SARI is in place to monitor respiratory infections (influenza, COVID-19, respiratory syncytial virus – RSV). For sentinel ILI and ARI surveillance, there is a known population denominator and coverage is approximately 30% of Serbia's population. For SARI sentinel surveillance, the coverage is estimated to be approximately 70% (nine sentinel hospitals are participating, encompassing infectious diseases clinics, paediatric clinics, and a hospital centre). However, it is challenging to estimate the precise population under surveillance as there are no catchment denominators available for participating hospitals. In addition to ILI, ARI and SARI sentinel surveillance, sentinel surveillance of AMR of human *Salmonella enterica* isolates is established at 18 sentinel sites (comprising laboratories from public health institutions and hospitals) in all regions of Serbia. It covers 28% of laboratories under the Ministry of Health, and around 82% of the population.

Procedures for external and internal evaluation of surveillance systems for communicable diseases are established. Internal evaluation of ILI, ARI SARI and West Nile fever (WNF) surveillance systems is conducted periodically by fellows from the Mediterranean and Black Sea Programme for Intervention Epidemiology Training (MediPIET). Sentinel surveillance of ILI/SARI was evaluated in 2018 and covered three seasons (2014/2015, 2015/2016, and 2016/2017) as internal evaluation. External evaluation of influenza surveillance in Serbia was performed in 2019 by the World Health Organization (WHO). In addition, several external evaluations were conducted or are planned, either assessing capacities for communicable disease surveillance overall [9, 10], microbiological surveillance [11], or surveillance of specific diseases [12].

2. Data collection

Serbia mostly applies EU 2012 case definitions for the reporting of communicable diseases. However, for some diseases (e.g. measles, hepatitis B and C, tuberculosis) a combination of EU 2012 [13] and WHO case definitions [14-16] is applied to balance between the sensitivity of the surveillance system to detect cases of disease and the proportion of identified cases who actually have the health event under surveillance (positive predicted value). Nonetheless, the process to adopt EU 2018 case definitions for communicable disease surveillance is ongoing, and EU 2018 case definitions are used for WNF, HIV infection/AIDS, hepatitis A and gonorrhoea. ILI, ARI and SARI cases are reported according to the WHO case definition.

The Institute of Public Health of Serbia 'Dr Milan Jovanovic Batut' (IPHS) has documents pertaining to case definitions available on its webpage, [18], as well as guidance on how to report cases of communicable diseases (in accordance with the Rulebook on Reporting of Communicable Diseases and Specific Health Issues) [19, 20] and disease reporting protocols (e.g. WNF, measles, influenza, *Clostridioides difficile* infection) [21, 22]. These documents, along with a user manual on the dedicated web-based reporting system for notifiable diseases (Public Health Service – PHS – managed by the IPHS) are disseminated to healthcare settings. Updated guidelines for WNF and influenza surveillance are disseminated in the beginning of each surveillance season. Even though reporting protocols are already available for all diseases under surveillance, the IPHS is trying to disseminate further relevant documentation to the private healthcare sector through the network of district public health institutes.

Notifiable communicable diseases are reported by medical doctors (nurses and laboratory staff can also report under medical doctors' supervision), which comprise public and private healthcare institutions (including those within prisons and the military), legal entities that provide healthcare services, and laboratories. Information is sent to district and national level institutes of public health, and then to the international level (e.g. reporting to The European Surveillance System – TESSy [23] and WHO). TESSy data reporting is simplified for some diseases, as reporting forms for national surveillance include all variables required for reporting at EU/EEA level (e.g. as aggregated ILI and SARI data), while for others (e.g. gonorrhoea, hepatitis A) additional data are collected through epidemiological investigation.

Case-based data for notifiable disease's surveillance are collected through a web-based system (PHS) with a central database. There is no automatic integration between clinicians' notification and laboratory results pertaining to pathogen detection, or presence of microbiological markers. Physicians receive directly (from laboratories) or indirectly (from patients) information about the microbiological findings and they record the respective information manually in the central database. Some data pertaining to laboratory results reported to doctors are collected in paper-based forms. Epidemiologists at district level and in hospitals should review all the reports in the PHS and update the case's classification, according to clinical, laboratory and epidemiological criteria collected *a priori*. The process is time consuming and, therefore, solutions are being studied for its automation, decreasing surveillance burden and possible human error.

Aggregated data are collected through standardised surveillance forms for other communicable diseases and health events under surveillance, such as ILI, ARI, at all hospitals participating in SARI surveillance, for syndromic disease surveillance among migrants, or during emergency situations or events of public health importance (e.g. mass gatherings, floods).

3. Data quality

Epidemiologists oversee the accuracy and validation of surveillance data by running quality checks and assessing data completeness (internal and external). Most surveillance variables are mandatory and checked for coding errors through an automated process. Therefore, internal data completeness is only assessed for non-mandatory surveillance variables and for some diseases (e.g. tuberculosis, polio, influenza, ILI, ARI, SARI). Notifiers can be contacted to specify data in case of missing or unknown values, keeping in mind a target of at least 80% of complete information [24]. The extent of under-reporting was assessed in 2010 for tuberculosis using the capture-recapture methodology [25]. It was estimated that approximately 10% of diagnosed tuberculosis cases were not reported (results are not publicly available). There are specific thresholds defined for laboratory data completeness (e.g. more than 80% of suspected measles cases should be laboratory-confirmed). The proportion of laboratory-confirmed cases out of the total number of reported cases in the surveillance system was assessed for several diseases and showed that WNF laboratory testing needs to be improved.

Timeliness thresholds for data quality are established and monitored for some diseases (e.g. AFP, measles, rubella). According to the Rulebook on Reporting of Infectious Diseases and Specific Health Issues [19, 20], suspected cases of cholera, plague, smallpox, yellow fever, viral haemorrhagic fever, SARS, poliomyelitis, diphtheria, botulism and unknown diseases should be reported immediately to public health authorities. For confirmed cases of notifiable diseases, microbiologists must report detected pathogens or microbiological markers within 24h and medical doctors must report diagnosed cases of disease within 24 hours of confirmation. Nevertheless, other steps within the chain of events from infection until reporting (e.g. delay between laboratory test request from the physician and laboratory diagnosis available to the microbiologist) at the district, regional or national public health services might present higher delays. Reporting timeliness of several communicable diseases presented a higher delay during the COVID-19 pandemic and the need for improvement has triggered dedicated actions. Among those, meetings with district and regional public health institutions were set up to gather overviews on timeliness, including its assessment, challenges and points for improvement. All meetings' minutes are shared with relevant stakeholders.

4. Data management

The Integrated Health Information System of the Republic of Serbia (IHIS) is regulated by the Law on Health Documentation and Records in the Field of Health [26] and is managed by the Ministry of Health. The authority for compliance with data protection and privacy legislation is the Commissioner for Information of Public Importance and Personal Data Protection. The main piece of legislation is the Law on Personal Data Protection [27], which for the most part follows the guidelines of the EU General Data Protection Regulation (GDPR) [28].

Data validation and cleaning are performed before removing personal information of surveillance data and replacing the personal number at birth by a unique pseudonymised code (patient ID). Even though there is no automatic integration between clinicians' notification and laboratory results, physicians reconcile clinical with laboratory information, as aforementioned. Thus, a unified and comprehensive view of surveillance data is provided to all users at all levels (district, regional and national) through a centralised database. There was an attempt during the COVID-19 pandemic to track and merge data across healthcare sectors, but it required too much effort.

There is no data linkage at national level between communicable disease surveillance and other surveillance systems, yet there are some attempts at local level to link communicable disease surveillance with immunisation data.

5. Data analysis

Epidemiological analysis of surveillance data, including disease notification rate and mortality trends, is performed annually for all diseases, monthly for relevant diseases, and weekly for respiratory viruses. Information from routine surveillance has been used to advise the national strategy for prevention and control of HIV/AIDS, implement disease mitigation measures during the COVID-19 pandemic (e.g. closure of schools), implement mosquito control and blood safety measures against WNF, update recommendations on pertussis immunisation (for pregnant women and booster dose for adolescents), and implement mandatory immunisation of healthcare workers against measles, mumps, and rubella (MMR). Risk factor studies, such as, predictors of influenza and COVID-19 hospitalisations or admission to intensive care units [29, 30], factors associated with multidrug-resistant tuberculosis or with tuberculosis treatment outcomes [30, 31], have also been used as a mean to build the scientific body of evidence on communicable diseases and inform public health decision-making.

Comparative analysis of national disease rates with EU/EEA rates to detect significant differences that could signal data quality issues is performed for diseases with comprehensive surveillance, using as denominator the population estimates from Bureau of Official Statistics [32]. Nonetheless, as age-standardised disease rates are not computed, disease rates between Serbia and EU/EEA may not be directly comparable and differences between surveillance systems are harder to interpret.

6. Dissemination of surveillance data

There are no automated surveillance dashboards or reports, but surveillance outputs are shared with all relevant stakeholders, at district, regional and national levels. Weekly, monthly and annual surveillance bulletins or reports are available on the IPHS website, accessible through Google Drive, or are shared by email to the IPHS surveillance network, the Ministry of Health, National Health Insurance Fund, Statistical Office of the Republic of Serbia, and other relevant national institutions and organisations. In case of outbreaks, or emerging diseases, ad-hoc reports can also be compiled and shared. In addition, several surveillance outputs are available for the general public in the IPHS website, including weekly bulletins on the epidemiological situation for influenza or COVID-19 [33-35], and annual reports on communicable diseases [36].

7. Outbreak detection

According to the Regulation on the Program for the Protection of Health of the Population against Communicable Diseases [37], epidemiologists are trained to recognise and assess the risk of outbreaks of communicable diseases. However, only general criteria are defined and specific pre-defined thresholds are only used for ILI surveillance with the Moving Epidemic Method - MEM [38].

Reporting of outbreaks by epidemiologists to national level and sanitary inspectors is performed in accordance with the Rulebook on Reporting of Infectious Diseases and Specific Health Issues [19, 20].

There is an early warning system (ALERT - System for Early Detection of Outbreaks of Infectious Diseases) that is introduced in specific situations [19, 20], with at least one person on duty 24/7 at national and district level. In case of a public health emergency more resources can be mobilised. It is a syndromic surveillance system that includes monitoring of acute respiratory infections, acute gastrointestinal symptoms, rash and fever, meningoencephalitis, acute jaundice, unexplained fever and haemorrhagic fever. Molecular surveillance for detecting clustering cases and outbreaks of disease is not routinely implemented and is only used for research studies. In 2023, pertussis [39] and measles [40] outbreaks were detected through indicator-based surveillance. Additionally, there is a monitoring system for early detection of outbreaks in the migrant population.

8. Capacity

Diagnostic confirmation and pathogen identification is not available for three diseases listed in the European Commission Implementing Decision 2018/945 [41]: Variant Creutzfeldt-Jakob disease, plague and smallpox. In addition, for Ebola and Marburg disease, there is no laboratory capacity to confirm suspect cases. Some reference laboratories have cooperation with laboratories in other countries to enable confirmation of these diseases, but as the agreements are made pro-bono there is no specific budget allocated.

Trainings for communicable disease reporting, analysis and outbreak investigation are offered mainly for epidemiologists, for e.g. through international cooperation (WHO, Network for Communicable Disease Control in Southern Europe and Mediterranean Countries – EpiSouth Network, Mediterranean and Black Sea Programme for Intervention Epidemiology Training – MediPIET). These trainings are not offered on a regular basis for all diseases, but for some disease networks or institutions they are offered annually, for example staff of the Institute of Virology, Vaccines and Sera – Torlak participate on a regular basis in annual meetings and workshops organised by the WHO and other networks, in which they receive training on the reporting of laboratory results. Through continuous medical education, clinical staff also are provided with training on the reporting and importance of notifying communicable diseases and healthcare-associated infections.

Bioinformatics capacity and availability of statistical software for data management and analysis of surveillance data is scarce. Serbia is trying to build its capacity in using free software for statistical computing, such as R [42]. Microbiology capacity is acceptable, nonetheless, an aging staff, lack of external quality assurance and validation procedures are challenging for communicable disease surveillance.

Conclusions and recommendations

This country visit brought together several surveillance experts from the IPHS, triggering a comprehensive discussion on national communicable disease surveillance in Serbia and enabling a clear view of the current situation by the ECDC team. Surveillance of communicable diseases in Serbia is a public health core function, regulated through national legislation. In recent years, efforts have been made to revise surveillance systems, make use of electronic health records, explore automated reporting and undergo surveillance evaluations to improve the systems' performance. However, progress is still ongoing and surveillance burden for data providers is not ideal. Strengthening laboratory capacities, leveraging knowledge on statistical computing, and fostering strong collaborative relations among public and private surveillance stakeholders could also be vital for improving timeliness of the surveillance systems and outbreak detection. This assessment has, consequently, led to the following recommendations proposed by the ECDC team, which are seen as concrete steps to improve disease surveillance in Serbia.

Revise case definitions

Continue revising and harmonising case definitions in line with the most recent European legal framework (Commission Implementing Decision (EU) 2018/945 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions) [41]. Of note, a revised list of notifiable diseases at EU/EEA level is expected in 2025.

Decrease surveillance burden for data providers

Consider automatic integration of clinical and laboratorial data, focusing on digitalisation and reducing the burden of notification. Continue investigating solutions for automation of cases of disease classification and integration of additional data required for TESSy reporting, decreasing surveillance burden and chance of human error for epidemiologists.

Strengthen laboratory capacity

The national reference laboratory should support diagnostic laboratories in standardising their methodologies and providing an external quality assurance scheme. Ideally, diagnostic confirmation should be available for all diseases to be covered for epidemiological surveillance listed in the European legal framework [41]. However, if for rare diseases consider formalising agreements for sending samples to laboratories in other EU countries in case of need. Consider leveraging the experience and expertise of older staff by offering continuous professional development and retraining, focusing on technology and digital tools.

Automate data processes and output production

Strengthen R programming capacity among data managers and epidemiologists with the aim of automating data validation, TESSy reporting (EpiPulse cases), compiling surveillance dashboards and performing statistical analysis. ECDC could provide support for training activities.

Improve notification timeliness

Consider elaborating further lessons from notification timeliness delays identified during the COVID-19 pandemic and continue to facilitate meetings with stakeholders involved in surveillance to gather overviews. Continue to monitor notification timeliness regularly and consider stratifying data by age and gender to investigate if there is a possible association between notification timeliness and demographic group of disease cases.

Enhance outbreak detection

For disease surveillance, consider prioritisation of laboratories that have molecular surveillance capacity, guided by the ECDC strategic plan for integrated genomic typing [43]. Explore algorithms such as CUSUM, EARS or Shewhart charts, with the aim to establish formal thresholds for outbreak detection [44].

Promote participation of private healthcare providers

Consider solutions to strengthen the relationships and collaboration with private health institutions on the surveillance of communicable diseases. One solution could be collaborative agreements and nominated contact points in private public health institutions to facilitate communication and dissemination of surveillance guidelines.

Estimate population under observation for SARI sentinel surveillance

Estimates of catchment population for SARI surveillance could be computed if hospital admission records, hospital registries, billing datasets, or other administrative datasets that have patients' address of SARI cases are available [45].

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Annex 1. Practical arrangements for the assessment process

This annex aims at describing the main practical arrangements of country visit to Serbia that took place in Belgrade from 8 to 10 April 2024.

Country visit agenda

| Day 1, 8 April 2024 | | |
|----------------------|---|--|
| Time | Topic | Participants |
| 12.35 | Estimated arrival of ECDC team at Belgrade airport | |
| 14.00–14.30 | ECDC team meeting with the representatives from Ministry of Health and IPHS Director Welcome and introduction to the meeting | |
| 14.30–15.15 | Surveillance of infectious diseases at EU/EEA level and strengthening surveillance in Western Balkans | Julien Beauté |
| 15.15–15.30 | Coffee break | |
| 15.30–16.00 | Description of infectious disease surveillance system in Serbia Discussion | Danijela Simic IPHS of Serbia, ECDC |
| Day 2, 9 April 2024 | | |
| 9.00–10.00 | Data collection | IPHS of Serbia, ECDC |
| 10.00–11.00 | Data quality | IPHS of Serbia, ECDC |
| 11.00–12.00 | Data management | IPHS of Serbia, ECDC |
| 12.00–12.30 | Lunch | |
| 12.30–13.30 | Data analysis | IPHS of Serbia, ECDC |
| 13.30–14.30 | Dissemination of the communicable disease surveillance data | IPHS of Serbia, ECDC |
| 14.30–15.30 | Outbreak detection | IPHS of Serbia, ECDC |
| Day 3, 10 April 2024 | | |
| Time | Topic | Participants |
| 9.00–10.00 | Discussion on selected diseases reported to ECDC | IPHS of Serbia, ECDC |
| 10.00–11.30 | Training on TESSy reporting in the context of new EpiPulse portal Reporting of existing diseases, Q&A Additional topics, Q&A | Adrian Prodan, IPHS of Serbia |
| 11.30–12.00 | Debriefing session: Draft conclusions and way forward | IPHS of Serbia, ECDC |
| 13.00–14.00 | Working lunch break with EU Delegation to Serbia, Dr Maja Vuckovic-Krcmar, Medical Advisor – Programme Officer – EU Policies/Horizontal coordination and Health | ECDC team |
| 14.15 | Leaving for the airport | ECDC team |



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