CAPACITY/CAPABILITY ASSESSMENT

ECDC country visit to Kosovo to discuss surveillance of communicable diseases

ECDC Accession Support to Western Balkans and Türkiye

Introduction

The European Centre for Disease Prevention and Control (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 the work of the Centre.

The aim of technical cooperation with countries in the Western Balkans and Türkiye [1] is to support their capacity 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:

- 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;
- 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 Kosovo[1] in March 2025 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 during the assessment mission were used to identify areas where surveillance operations could be further strengthened and those elements that could benefit from ECDC's technical support or guidance.

[1] This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

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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 is needed of how the national surveillance systems are organised 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 Kosovo. The offer was accepted and the agenda for the visit was developed jointly with the National Institute of Public Health of Kosovo (NIPHK). During the visit, findings for all areas of surveillance were discussed and the assessment tool was completed 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

Prevention and control of infectious diseases in Kosovo is regulated by Law No. 08/L-200 [5]. Annex 1 of this Law specifies 82 notifiable diseases and pathogens, and nine syndromes that are under surveillance. The list is partially based on the Commission Implementing Decision (EU) 2018/945 of 22 June 2018 [6] and includes additional diseases relevant to the public health situation in Kosovo. The Law also specifies the timing of notification for each disease, including those that require early warnings. Law No. 08/L-200 allows for the inclusion of new diseases as needed, based on recommendations by the NIPHK.

At national level, surveillance is coordinated by the Epidemiology Department of the NIPHK. Collaboration with food safety authorities, veterinary services, and environmental surveillance teams is in place to align communicable disease monitoring with these other domains. Data sharing with other sectors, such as mortality surveillance, blood and tissue safety (e.g. HIV identification in transfusion testing) and non-communicable disease surveillance, is generally reported to be effective, although the legal framework for these intersectoral exchanges could be strengthened.

Kosovo's communicable disease surveillance system is predominantly indicator-based, relying on passive surveillance for most notifiable diseases. Coverage is nationwide, with mandatory reporting requirements for both public and private healthcare providers at all levels (primary, secondary, and tertiary). Active surveillance can be initiated during outbreaks. Event-based surveillance is carried out routinely by the Epidemic Intelligence Committee. Sentinel surveillance is in place for influenza-like illness (ILI), acute respiratory infection (ARI) and severe acute respiratory infection (SARI) since 2014. Laboratory testing is performed for influenza, COVID-19 and respiratory syncytial virus (RSV). Data are reported from five sentinel sites across the two most populous regions, covering 48.4% of the population. Population estimates are available for these regions, via population census and annual population estimates [7]. Internal evaluation of ILI/ARI and SARI sentinel surveillance is routinely performed by epidemiologists at NIPHK.

Syndromic surveillance is in place for diarrhoeal and meningeal syndromes, acute flaccid paralysis, SARI and lower respiratory tract infections (LRTI). The complete list of syndromes and their description is listed in Annex 1 of Law 08/L-200. The law specifies the implementation of a 24/7 surveillance duty, which was in place until it was recently cancelled for budgetary reasons. At present, Saturdays are covered by an on-duty epidemiologist, but not Sundays.

Data sources for routine surveillance include local and regional public health authorities, general practitioners, hospitals and laboratories. Although no formal mechanism for the systematic evaluation of the surveillance system exists, Kosovo has participated in multiple assessments and evaluations, both internal and external. An ECDC assessment of the surveillance system was performed in 2018. An all-hazard risk assessment was performed in 2019 at both national and regional levels using the World Health Organization's STAR tool [8]. An intra-action review of COVID-19 surveillance took place in 2021. Kosovo participated in a Joint External Evaluation [9] in 2023 [10], focusing on the capacity to prevent, detect and rapidly respond to public health threats. In addition, an internal evaluation of SARI vaccine effectiveness was carried out from 2022 to 2024 by a fellow from the Mediterranean and Black Sea Programme for Intervention Epidemiology Training (MediPIET), currently working at NIPHK.

2. Data collection

A combination of paper-based and electronic reporting methods is currently used for infectious disease surveillance. Although a considerable part of the reporting is still paper-based, the new electronic system called 'Sistemi I Mbikëqyrjes së Sëmundjeve Ngjitëse' (SMSN) has been rolled out with several functional components, such as case report forms, basic dashboards, and epidemiological investigation forms [11]. It is anticipated that SMSM will be fully implemented by 2026, and training for healthcare professionals is already underway. Reporting responsibilities lie primarily with medical doctors and laboratory staff. SMSN reporting is currently available to public healthcare providers only, however private facilities should be included in 2025–2026.

Case definitions are published online, making them readily available to all health professionals tasked with reporting notifiable diseases [5]. In addition, SMSN offers guidance for clinicians and other healthcare workers on the process for reporting notifiable diseases at each level of the healthcare system.

At the national level, there is direct manual entry of new surveillance data. Paper-based records are digitised for analytical and dissemination purposes, such as generating case counts or performing trend analyses for seasonal influenza. At present, the paper-based system collects both aggregated and case-based data: diarrheal syndromes, varicella, and ILI/ARI data are aggregated, whereas other notifiable diseases are reported on an individual case basis. As SMSN continues to expand, all diseases under surveillance are expected to transition to case-based reporting. Each disease has a specific reporting form containing relevant clinical and laboratory variables, including all those required for TESSy/EpiPulse reporting.

Some surveillance data are shared with internation organisations such as ECDC or WHO.

SMSN is integrated with healthcare providers at all three levels of the health system. Integration is based on the personal national identification number and ICD-10 codes for the disease. When a patient's ICD-10 code matches one of the notifiable diseases, the epidemiologist responsible for the investigation can access the corresponding healthcare provider's records. Laboratory data from private laboratories are currently not included in SMSN.

3. Data quality

Data quality is regularly assessed using established procedures. Each disease or group of diseases is overseen by an epidemiologist at the NIPHK. Data are checked for variable coding errors, detection of duplicate entries, and confirmation of logical consistency in the reported data. Similarly, data gaps and unknown values are evaluated at both the national and regional levels to maintain data integrity.

Within the paper-based system, certain validation steps are impractical or impossible. For diseases with aggregated data reporting, duplications may be overlooked if each provider includes the same patient in its aggregate report, for instance when a person visits multiple healthcare providers. Similarly, spotting human errors such as misreporting or incorrect coding in case report forms is more difficult without digital verification tools.

Timeliness is monitored for SARI surveillance, but only at the national level. Delays from the regional to the national level are commonly observed. It is unclear whether SMSN will include automated timeliness monitoring in the future.

SMSN already offers partial automated data validation, such as enforcing required fields and automatically linking patient data through national identification numbers. Over time, these validation processes will be extended at national, regional and local levels, contrasting with the current paper-based system, where validation is mostly carried out at the national level. In addition, SMSN accommodates manual data entry for individuals who do not have a Kosovo personal identification number.

Although timeliness thresholds for each notifiable disease are defined by law [5], there is no mechanism to ensure or measure compliance with these standards. Similarly, no minimum benchmarks for completeness or other data quality measures have been set, resulting in limited incentives for systematic improvement.

For ILI, ARI and SARI, the proportion of laboratory-confirmed cases among reported cases is routinely examined, and a similar approach was used for COVID-19 during the pandemic. However, apart from these diseases there are no other analogous quality assessments carried out on a routine basis.

Regular feedback on data quality is not yet provided to the facilities that submit data. Instead, biweekly EpiTel conferences serve as a forum for discussing data-related issues and questions. If systematic data quality problems arise at a particular facility, the national team contacts the provider directly to resolve the issue.

A small set of eight to 10 municipalities, representing 2.31% of Kosovo's population from the last census, where most residents are of Serbian ethnicity, does not report to the country's institutions, with the exception of some COVID-19 cases which were reported during the pandemic.

4. Data management

In line with the EU General Data Protection Regulation (GDPR) [12], the Ministry of Health acts as the owner of surveillance data, while the NIPHK acts as the data controller. Kosovo has adopted the GDPR provisions, as reflected in Article 11, Paragraph 1 of Law 08/L-200: 'Personal data will be processed in accordance with the legislation in force and in accordance with the EU General Data Protection Regulation' [5]. International data reporting obligations are further outlined in Article 21, Paragraph 9 of the same Law, stating that 'NIPHK reports to ECDC and other international institutions through officials appointed by the Minister, on a regular basis according to the criteria set by ECDC and other international institutions'.

At present, the SMSN is the only authorised digital platform for collecting and using surveillance data on infectious diseases, and paper-based reporting will continue until the full transition to SMSN is complete. Clinical data are entered by medical doctors, laboratory data by laboratory staff, and epidemiological investigation data by epidemiologists across all levels of the healthcare system. Under the paper-based system, it is not possible to track a patient across different tiers of the healthcare system (e.g. from primary to secondary or tertiary care). In contrast, SMSN will allow ongoing case tracking through the use of personal identification numbers, and demographic information will be automatically retrieved from the Agency for Civil Registration. Future integration with the vaccination registry and non-communicable disease surveillance data (e.g. ICD-10 codes recorded in primary care) is planned, and historical records will also be migrated into SMSN.

For laboratory data, linkage to patient records is possible, but not yet fully automated. Epidemiologists access laboratory results through a specialised information system known as MedLIS, extracting data as needed to complete case investigations. All epidemiologists can view identifiable personal data, except in the case of HIV, for which pseudonymisation is enforced. There is a plan to integrate SMSN with MedLIS and a vaccination module. In addition, SMSN will be expanded to include zoonotic disease under a One-Health approach. At this point, it is yet to be determined whether recognised data interoperability standards (e.g. HL7 or FHIR) will be incorporated into SMSN's technical requirements.

5. Data analysis

Epidemiological descriptive analyses are routinely conducted using surveillance data, primarily focusing on the total number of reported cases and both total and age-specific incidence rates at the national and regional levels. Population estimates from the National Statistics Office [7] are used as denominators for calculating these rates. For diseases reported to ECDC, comparisons are made between national and European Union/European Economic Area (EU/EEA) incidence rates to detect anomalies or data quality concerns.

Routine trend analysis is performed for influenza and other respiratory diseases, serving as the basis for public health recommendations such as the reinforcement of protective measures if influenza activity is on the rise [13]. In contrast, such trend analyses are not consistently applied to other notifiable diseases. During the COVID-19 pandemic, forecasts of case numbers were developed to guide response strategies and policy decisions.

At present, all routine analyses are carried out manually. However, SMSN plans to introduce a monitoring dashboard that will offer automated descriptive statistics. Despite these forthcoming improvements, two main barriers to data analysis are identified by epidemiologists: the absence of fully digitised surveillance records and the overall scarcity of resources.

6. Dissemination of surveillance data

The National Institute of Public Health of Kosovo (NIPHK) produces a range of public outputs to convey surveillance findings to both healthcare stakeholders and the broader community. These outputs include weekly bulletins on seasonal influenza [13], monthly [14] and annual communicable disease bulletins [15] and annual NIPHK reports [16] that cover a variety of health topics beyond communicable diseases. All publications are available online through the NIPHK website [17]. Although dissemination is overseen at the national level, disease data are further broken down at the regional and district levels to highlight geographical variations in disease incidence. Weekly influenza bulletins offer recommendations to stakeholders, guiding policy and practice based on recent epidemiological trends.

During the COVID-19 pandemic, a semi-automated dashboard provided timely updates on key epidemiological indicators. Additional materials, such as ad hoc announcements, outbreak reports, and recommendations for emerging threats such as mpox, are released as required.

7. Outbreak detection

Outbreak detection in Kosovo relies on routine surveillance data. Each day, epidemiologists review notifications and track the number of reported cases by disease. For most diseases, the counts for the current month are compared to those from the same month in the previous year as a baseline, although no extended time series analysis is performed. In contrast, respiratory diseases are monitored with time trend calculations and more comprehensive analyses. Standard outbreak detection criteria apply, including the occurrence of two or more cases of the same disease linked in time and place, or any single case of an unusual disease or unexpected health event. For seasonal influenza, a defined epidemic threshold is also observed [13].

When an outbreak is detected locally, the local epidemiologist alerts the regional authorities, who in turn report to the national authorities. There is established guidance for outbreak investigation. In 2024, multiple foodborne disease outbreaks occurred in Kosovo, with a total of 687 exposed individuals and 148 who became ill.

At present, molecular surveillance for outbreak detection is not routinely conducted for all diseases, mainly due to financial constraints.

8. Capacity

Diagnostic confirmation and pathogen identification for commonly encountered diseases in Kosovo is generally available, but limitations in funding and resources inhibit capacity for less prevalent diseases. The microbiology laboratories of the NIPHK operate at Biosafety Level 2 (BSL-2). Pathogens such as Crimean-Congo haemorrhagic fever (CCHF) and *Mycobacterium tuberculosis* are tested at BSL-2 level while adhering to BSL-3 protocols.

Molecular surveillance capabilities expanded substantially during the COVID-19 pandemic, incorporating three next-generation sequencing (NGS) platforms and multiple RT-PCR systems. There is capacity for molecular surveillance for respiratory pathogens, tuberculosis, HIV, hepatitis B and C, and emerging diseases such as CCHF, haemorrhagic fever with renal syndrome (HFRS), mpox and others. The main obstacle to real-time sequencing on a routine basis is the high cost involved. In the past there have been instances where testing kits for infrequently screened pathogens were not available. Cooperation with reference laboratories is in place – e.g. the World Influenza Centre in London (for SARI) and the Bernhard Nocht Institute for Tropical Medicine in Germany (for tropical diseases). However, there are few incentives in place for private laboratories to ship their specimens for further characterisation (e.g. shipping costs not reimbursed).

All medical residents, epidemiologists and selected healthcare professionals undergo basic epidemiology training, including communicable disease reporting procedures. Training on communicable disease case definitions and reporting was recently conducted in conjunction with the roll-out of SMSN. In 2024, epidemiologists from NIPHK participated in a Joint Assessment and Detection of Events (JADE) exercise [18].

Essential human resource gaps persist in the public health sector. The number of available epidemiologists is limited, and it is often a struggle to attract qualified candidates for public sector vacancies. There are no bioinformaticians, due to the fact that local training programmes are not available in Kosovo. No administrative staff are employed within departments, although there is a Department of Administration at NIPHK. More sophisticated statistical analyses (e.g. advanced time-series or geographic methods) are beyond current capacity. There is a department of statistics at NIPHK, however this focuses on non-communicable diseases.

In addition, the lack of statistical software packages further inhibits the ability to conduct in-depth epidemiological analyses.

Conclusions and recommendations

This country visit brought together several surveillance experts from the NIPHK, triggering a comprehensive discussion on national communicable disease surveillance in Kosovo and providing the ECDC team with a clear understanding of the current landscape. Communicable disease surveillance in Kosovo is a core public health function, governed by a robust law on prevention and control of infectious diseases.

The country is currently making a nationwide effort to digitalise, with the migration from a paper-based system to an electronic surveillance system that integrates data from multiple sectors, at all levels of healthcare. The new system is also expected to automate data analysis and facilitate data quality and system evaluation. However, during this transition period, the data reporting burden remains a challenge.

Enhancing laboratory and human resource capabilities, utilising expertise in statistical computing, and fostering strong collaboration between public and private surveillance actors could be crucial to improving the timeliness and responsiveness of the system. Based on this assessment, the ECDC team has put forward a set of recommendations viewed as practical steps toward strengthening disease surveillance in Kosovo.

Continue the digitalisation progress with SMSN

Maintain momentum in the SMSN rollout. Finalise and expand digital reporting to all healthcare providers, public and private, ensuring that transitioning facilities receive adequate training and resources.

SMSN will probably not be able to accommodate all specialised surveillance activities (e.g. vaccine effectiveness analysis, risk factor analyses, other disease specific in-depth analyses). These activities should be safeguarded by allowing the use of complementary systems such as GoData [19], REDCap [20] or others, if SMSN cannot accommodate all variables or protocols.

Ensure comprehensive data migration from historical paper-based records into SMSN to avoid gaps during the transition phase.

The digitalisation process is an opportunity to start providing timely data quality feedback to local and regional levels, including private healthcare providers, to foster continuous improvement in reporting.

Automate data processes and data quality monitoring

Ensure that SMSM implements data validation procedures (e.g. duplicate detection, required fields, logical consistency checks) to reduce manual workloads for data providers and analysts. Routine monitoring of timeliness and data completeness should be introduced, setting clear thresholds and follow-up actions (e.g. refresher training where completeness is below the defined threshold).

Enhance data analysis capacity

Expand training in statistical and epidemiological methods (e.g. time-series analysis, formal outbreak detection algorithms) to enable more sensitive early-warning systems.

Strengthen laboratory capabilities and coordination

Diagnostic confirmation should ideally be available for all those diseases to be covered for epidemiological surveillance listed in the European legal framework [6]. For rare diseases, it might be more realistic to consider formal agreements with reference laboratories in other countries, as required.

Strengthen human resource capacity and capabilities

Address the shortage of trained epidemiologists, data scientists, and bioinformaticians by offering specialised training pathways and competitive incentives. Encourage intersectoral collaboration (human health, veterinary, environmental) to cross-train staff, share expertise, and optimise available resources. Explore partnerships with academic institutions for tailored courses, including advanced epidemiology and informatics modules.

Use free software for statistical computing (e.g. R [21], Jamovi [22], Orange [23]). Take advantage of the many training courses available online for free or provided by other institutions, such as ECDC.

Ensure up-to-date guidance documents and training materials are readily available via SMSN and the NIPHK website, streamlining clinical and laboratory reporting.

Increase participation of private healthcare providers

Align private sector reporting obligations with national standards, providing explicit guidelines, digital access to SMSN, and data submission requirements.

Establish dedicated contact points or focal points in private facilities to strengthen communication and improve surveillance data flows.

Incorporate private laboratories into molecular surveillance efforts, where feasible, to capture a wider range of testing data.

Review and harmonise national case definitions

Continue aligning Kosovo's list of notifiable diseases and case definitions with Commission Implementing Decisions. It should be noted that an update to Commission Implementing Decision (EU) 2018/945 [6] is expected by 2025, with a revised list of notifiable diseases.

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Annex 1. Practical arrangements for the assessment process

This annex describes the main practical arrangements of the country visit to Kosovo that took place in Pristina from 5 to 6 March 2025.

Country visit agenda

Day 1 – 5 March 2025		
09:00 – 09:30	Welcome and introduction to the meeting	NIPHK, ECDC
09:30 – 10:00	Surveillance of infectious diseases at EU/EEA level and strengthening surveillance in Western Balkans	NIPHK, ECDC
10:00 – 10:30	Presentation: Description of infectious disease surveillance system in Kosovo	NIPHK, ECDC
10:30 – 10:45	Break	NIPHK, ECDC
10:45 – 12:00	System description	NIPHK, ECDC
12:00 – 13:00	Lunch break	NIPHK, ECDC
13:00 – 14:00	Data collection	NIPHK, ECDC
14:00 – 15:00	Data quality	NIPHK, ECDC
15:00 – 16:30	Data management	NIPHK, ECDC
Day 2 – 6 March 2025		
09:00 – 10:00	Data Analysis	NIPHK, ECDC
10:00 – 10:45	Dissemination of the communicable disease surveillance data	NIPHK, ECDC
10:45 – 11:00	*Break*	NIPHK, ECDC
11:00 – 11:45	Outbreak detection	NIPHK, ECDC
11:45 – 12:30	Capacity	NIPHK, ECDC
12:30 – 13:00	*Lunch break*	NIPHK, ECDC
13:00 – 14:00	Discussion on selected diseases reported to ECDC	NIPHK, ECDC
14:00 – 16:00	Training on EpiPulse CASES/TESSy reporting in the context of new EpiPulse portal. Reporting of existing disease, Q&A Challenges and other issues, Q&A	NIPHK, ECDC
16:00 – 16:30	Debriefing session: Draft conclusions and way forward	NIPHK, ECDC

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