ECDC

PHF/Surveillance/MMS

Draft ECDC concept for integration of wastewater data in surveillance of infectious diseases at EU/EEA level

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Document purpose

In alignment with the Long-term surveillance framework 2021–2027 (1), the European Centre for Disease Prevention and Control (ECDC) proposes a concept for the integration of wastewater data into EU-level surveillance of infectious diseases. The document will be used as background for discussions with key stakeholders including ECDC National Focal Points for surveillance and microbiology, ECDC Advisory Forum, the European Commission and key stakeholders engaged in wastewater surveillance in the EU/EEA.

**Abbreviations**

AMR Antimicrobial resistance

CCB Coordinating Competent Body structure

DEEP Digital European Exchange Platform

DG ENV Directorate-General for Environment of the EC

DNA Deoxyribonucleic acid

EC European Commission

ECDC European Centre for Disease Prevention and Control

EEA European Economic Area

EU European Union

EU-WISH EU-Wastewater Integrated Surveillance for Public Health

EQA External quality assessments

GLOWACON Global Consortium for Wastewater and Environmental Surveillance for Public Health

HERA Health Emergency Preparedness and Response

JRC Joint Research Centre

NFP National Focal Point

OCP Operational Focal Point

PCR Polymerase chain reaction

RNA Ribonucleic acid

WBS Wastewater-based surveillance

WHO World Health Organization

UNEP United Nations Environment Programme

Summary

* Wastewater-based surveillance (WBS) has proven useful for monitoring of poliovirus, SARS-CoV-2, influenza and other pathogens. It can provide informative infectious disease surveillance data for risk assessments and public health decision making. WBS of infectious diseases can complement data from indicator- and event-based surveillance and should be interpreted and communicated in relation to data from these surveillance systems.
* The revised urban wastewater treatment directive will include a legal obligation for Member States (MS) to implement WBS and to establish communication and collaboration between relevant actors at the national level, including public health partners.
* Any WBS programme needs careful planning and design before implementation to ensure they address public health needs and fill current surveillance gaps.
* WBS for infectious disease surveillance will need to be placed and developed in context of the larger eco system of WBS application in collaboration with the European Commission.
* ECDC proposes to lead the consolidation and further integration of WBS as a complementary surveillance system for infectious diseases at EU level.
* ECDC suggests establishing a dedicated EU/EEA wastewater surveillance network within ECDC’s coordinating competent body structure, aiming to support a sustainable and flexible system that integrates WBS data into existing EU-level surveillance.
* Within this proposed wastewater surveillance network, ECDC suggests providing support activities to further strengthen data comparability and use.
* For effective integration into EU-level infectious disease surveillance, ECDC requires automated real-time access to electronic WBS data. As of now, WBS data collection at the EU level is insufficiently addressed and several possible solutions for databases and data collection systems are being discussed.
* Further consultations with key stakeholders, including European Commission services, ECDC Advisory Forum and National Focal Points for Surveillance and Microbiology are needed to assess the feasibility of this concept.

1. Introduction

ECDC has the mandate to identify, assess, and communicate current and emerging threats to human health from communicable diseases in the EU/EEA. Within this scope, ECDC collects, validates, analyses, and disseminates routine surveillance data on notifiable infectious diseases from 30 EU/EEA countries (2, 3 ). EU-level surveillance is based on reporting from national systems, with the aim to timely and effectively fight cross-border threats to public health from infectious diseases. Routine EU/EEA integrated surveillance outputs include the Surveillance Atlas of Infectious Diseases (4), the Annual Epidemiological Reports (5), daily and weekly communicable disease threat reports (6), a number of enhanced surveillance reports produced jointly with other EU agencies or the World Health Organization (WHO), weekly bulletins, online maps and articles in peer-reviewed scientific journals.

ECDC works closely with the Member States and coordinates disease or health-issue-specific networks for infectious disease surveillance in the EU/EEA. The networks include nominated national disease experts and public health function experts with cross-cutting roles in surveillance, threat detection and microbiology etc. Specifically for laboratory aspects, ECDC is mandated to “foster the development of sufficient capacity within the Community for the diagnosis, detection, identification, and characterisation of infectious agents which may threaten public health, by encouraging cooperation between expert and reference laboratories”. Under this mandate, ECDC coordinates EU-wide networks of microbiology laboratories embedded in disease-specific networks. They primarily contribute to integrated epidemiological and microbiological surveillance of EU-notifiable communicable diseases as well as to the detection of emerging diseases. To strengthen capacity within these networks, ECDC has offered support ranging from EU-wide laboratory network coordination, external quality assessments (EQA), laboratory staff training, establishment of reference microbial strain collections, supranational reference services, method harmonisation, development of standard procedures etc. These laboratory support activities are currently transferred to an EU reference laboratory model following updated legislation for infectious disease surveillance and control (2).

Wastewater-based surveillance (WBS) is a subset of the broader term environmental surveillance that may include other samples such as from air and soil. For the purpose of this document, wastewater refers to sewered municipal wastewater (sewage and greywater), which comprises liquid waste discharged by domestic residences and commercial properties but may include wastewater from industry, and/or agriculture and surface runoff. WBS has been used for decades and multiple targets including environmental surveillance of poliovirus since the 1980s (7), but the method regained interest during the COVID-19 pandemic for the surveillance of SARS-CoV-2 and its variants, especially in situations when clinical testing declined. WBS relies on the shedding of infection biomarkers (e.g. through faeces, urine, or respiratory secretions) into the sewage system in sufficient quantities and with adequate stability to enable detection. Municipal wastewater samples are collected, processed, and analysed, typically using PCR to detect specific DNA or RNA, although metagenomic sequencing is gaining popularity. Unlike clinical testing that tracks individual cases, WBS provides aggregate data from an entire community, detecting the presence and concentrations of pathogens. To increase comparability data normalisation is needed and often relative values are more comparable between sites. WBS has the potential to offer valuable data for infectious disease surveillance and can complement existing surveillance activities.

In the last years, the interest for WBS increased in the EU and the EU Commission launched several initiatives to explore and strengthen this approach. In 2021, the EU Commission published a Commission communication tasking HERA to strengthen genome sequencing and environmental monitoring including wastewater-based surveillance (8). The first initiatives were funded under the HERA incubator, with progressive efforts put in place in order to institutionalise wastewater surveillance for public health. To this end, since 2022, HERA has been working together with the JRC on several fronts, such as capacity building, development of technical guidance, trust-building, while closely engaging with EU Member States as well as international stakeholders, such as WHO, the Bill and Melinda Gates Foundation, UNEP.

Currently, despite the efforts carried out at EU level, the level of implementation of WBS systems and the capacity of these systems to inform public health action remains heterogenous in the EU/EEA countries (9). Systems have been set up with different population coverages, sampling frequencies, inclusion of pathogens and level of sustainability, originating mostly from time-limited projects and initiatives.

The European Urban Wastewater Treatment Directive is currently being revised and will set new requirements for EU/EEA countries to implement systems for routine WBS data collection, as well as for use during health emergencies. To strengthen harmonisation, Member States will be asked to consider recommendations from various stakeholders, including ECDC, when setting up national WBS systems. This ECDC concept paper aims to support Member States in developing national WBS systems and to provide a proposal for the use of WBS for EU-level infectious disease surveillance and public health decision making.

1. European key initiatives promoting wastewater surveillance

During the COVID-19 pandemic, the European Commission issued recommendations for a common approach to WBS of SARS-CoV-2 and launched several financial and technical initiatives to boost its use (8, 10). In parallel, also WHO identified WBS as a promising COVID-19 surveillance tool and issued guidance (11, 12).

# The recast Urban Wastewater Treatment Directive

On 29th January 2024, Council and Parliament reached a provisional agreement on the recast Urban Wastewater Treatment Directive (UWWTD) (13). Adoption of the final agreement is expected in November 2024, with entry into force by the end of 2024, with adoption to follow.

The recast UWWTD (14) regulates the collection, treatment and discharge of urban wastewater to protect the environment and human health. This revision of the Directive includes a new article (Article 17) on the surveillance of urban wastewater for public health parameters, including infectious diseases and antimicrobial resistance (AMR). Member States shall set up national systems for cooperation and coordination between competent authorities responsible for public health and those responsible for urban wastewater treatment. Proposed pathogens and health determinants to consider for national WBS include SARS-CoV-2, poliovirus, influenza virus, emerging pathogens and any other public health parameters considered relevant by the competent authorities of the Member States. Where a public health emergency is declared relevant public health parameters are to be monitored. In addition, Member States are to establish WBS for AMR and details including sampling frequency and methods will be specified in implementing acts within a specified time frame after adoption of the Directive. Member States need to ensure appropriate and timely communication of WBS results between relevant authorities and reporting to EU platforms, (including annual reporting to the EEA). The Commission is empowered to adopt implementing acts specifying the format of the information to be provided.

The recast Directive requires Member States to identify relevant public health parameters to monitor by means of urban wastewater surveillance, taking into account recommendations from ECDC, HERA, WHO and others.

# EU wastewater surveillance projects and networks

A series of EU initiatives have been launched by the European Commission, in particular by HERA in collaboration with the JRC, to facilitate and evaluate the use of WBS for infectious disease surveillance in the EU and beyond. These include the 2020 EU umbrella study for SARS-CoV-2 sewer surveillance (15), an expert consultation by WHO and the European Commission, the creation of the EU Wastewater Observatory for Public Health and its Digital European Exchange Platform (DEEP) (16), and direct grants of the EC as part of the HERA Incubator programme to member states (EUR 20 million) to implement WBS for SARS-CoV-2, The EU observatory interacts with a global network of national contact points and organises regular implementation meetings to improve harmonisation and enable exchange of best practices. DEEP links to national WBS resources, produces monthly SARS-CoV-2 WBS bulletins for the EU and selected countries globally. The platform facilitates interaction between JRC, HERA, other European Commission services, EU Member States and third countries, coordinating ad hoc exercises such as the 2023 airport and aircraft surveillance of SARS-CoV-2 (17) and bulletins on avian influenza or mpox in the EU/EEA (18).

The Joint Action EU-Wastewater Integrated Surveillance for Public Health (EU-WISH) (19), funded by HERA through the EU4Health programme (EUR 15 million), combines expertise from 25 EU/EEA countries and Ukraine to strengthen national capacities for wastewater surveillance for public health. The consortium consists mainly of representatives from national public health bodies. It will map priority targets for WBS and define, harmonize and expand wastewater monitoring strategies, technical procedures and relevant operational approaches.

Launched by HERA in collaboration with the JRC, a Global Consortium for Wastewater and Environmental Surveillance for Public Health (GLOWACON) was established in 2024 to promote best practices and foster global collaboration. GLOWACON aims to establish an international sentinel system for early detection and monitoring of epidemic threats (20). As a European component, a call for tender funded by HERA through the EU4Health programme (EUR 32 million over four years) has been launched to procure services for measuring emerging pathogens and pollutants in untreated wastewater at strategic locations, forming a sentinel super-site network (21).

# The need for cross-sectoral coordination

One of the most innovative and complex aspects of WBS for the surveillance of communicable disease from a public health perspective is that samples are taken from the environmental sector. This has various implications in terms of required coordination, namely:

* public health agencies and authorities do not necessarily have the competence and resources to access wastewater sampling sites, and to collect and process wastewater samples;
* results obtained from environmental sample can not only reflect the health status of surrounding human population, but can also be influenced by that of the domestic or wild animal population;
* WBS can be relevant for the surveillance of other threats than communicable diseases, e.g. chemical contamination or (illicit) drug consumption;

Consequently, the initiative of ECDC to developing WBS for infectious disease surveillance needs to be well coordinated with other initiatives of the European Commission and agencies engaging in WBS for the surveillance of other threats than communicable diseases and/or for the surveillance of animal and environmental health.

1. The role of WBS in public health

WBS has been identified as an approach capable of providing useful complementary data for infectious disease surveillance and scientific evidence and has substantially increased in the wake of the COVID-19 pandemic. While WBS comes with its own limitations and challenges, it also circumvents a number of biases present in clinical and epidemiological surveillance. It provides a non-invasive and anonymous method for regularly tracking the presence of pathogens within a community independent of the availability or uptake of clinical testing or the population’s healthcare-seeking behaviour. WBS is largely symptom agnostic if both asymptomatic and mildly symptomatic individuals shed pathogen-containing material into the sewage system and contribute to the wastewater signals. Once sample collection and processing are established, the presence of multiple pathogens can be detected from a single sample increasing the cost-effectiveness where pathogen-specific WBS programmes align sufficiently. The surveillance population can be adjusted based on the wastewater treatment plant's catchment area or targeted sampling points. Detection assays such as PCR allow a high flexibility to quickly adapt WBS systems to include additional emerging pathogens. Of note, WBS can also be used to monitor chemicals, pharmaceuticals, and narcotics in water. However, this report focuses only on WBS for infectious diseases and related health issues. Continued operational and applied public health research is essential for enhancing and advancing WBS. Both bio-banked and prospectively collected samples can be helpful in studying relevant public health questions such as spread and distribution of pathogens or AMR over time or to improve detection methods etc.

# WBS as complement to routine infectious disease surveillance

WBS has demonstrated public health value when complementing routine infectious disease surveillance. It can support monitoring of disease trends including early warning signals, detection of outbreaks, genomic surveillance and evaluation of the effectiveness of public health measures. The WHO, through the Global Polio Eradication Initiative, has advocated for and supported implementation of environmental surveillance of poliovirus globally (22) and actual needs for production of additional guidance and/or further integration with ECDC surveillance programmes will have to be carefully evaluated.

* **Monitoring and early warning of disease trends:** Community or sentinel wastewater surveillance systems can provide insights into infection trends making them a potentially valuable complement to other surveillance data. Examples include national monitoring of the spread of SARS-CoV-2 in many EU/EEA Member States (23) and such data often correlating with clinical testing data and providing early warning signals of increases in clinical cases or hospitalisations (24-26). Likewise, WBS of influenza virus has been useful for national influenza A virus surveillance (27, 28) including early warning of epidemic waves (27).
* **Detection of unusual events and outbreaks:** Routine WBS helps establish baseline data to detect unusual events and potential outbreaks, such as a city-wide influenza outbreak in Ottawa (28) or the detection of circulating vaccine-derived poliovirus in London wastewater in early 2022 (but no cases of paralytic polio), which prompted increased immunisation efforts and may have prevented an outbreak (29) (30). In July 2024, presence of circulating vaccine-derived poliovirus was confirmed in wastewater in the Gaza Strip and triggered an immunisation campaign (31).
* **Genomic surveillance:** WBS has the potential to support genomic surveillance of target pathogens or health issues such as AMR. For example, variants of SARS-CoV-2 could be successfully tracked in many places including Rotterdam wastewater (32). In Ottawa, influenza virus from wastewater samples could be typed and influenza A virus subtyped which may allow to monitor type and subtype distributions along an influenza season (28).
* **Evaluation of public health interventions:** WBS can support assessment of the effectiveness of public health measures by tracking changes in pathogen levels in wastewater, where such changes would be expected, and informing policy decisions. WBS of SARS-CoV-2 has been suggested for early warning of resurgence or to identify pockets of community transmission as opportunities for vaccination campaigns (33). Another example is WBS of poliovirus to support verification of absence of disease in the context of eradication programmes (34).

# Enhanced surveillance

Settings with established WBS can enhance their system to respond to specific triggers or events to fulfil mostly national surveillance objectives and respond to changed needs short term. This includes increasing the sampling frequency, fast-tracking analyses and reporting workflows, increasing or changing population coverage, modifying or adding genomic surveillance aspects etc. Enhanced WBS offers a time-limited response that can provide value to integrated disease surveillance. Below are examples where WBS has been adapted for specific situations:

* **Mass gathering events:** WBS can provide cost-effective, anonymous, non-invasive and convenient additional surveillance data during mass gathering events such as large sport events. The French National Public Health Agency identified priority pathogen targets relevant and feasible for monitoring during the Olympic and Paralympic Games in Paris in 2024 and presented a model framework for identifying context-specific wastewater surveillance targets for mass gathering events (35).
* **Monitoring of high-risk population:** By targeting specific sites like hospitals, long-term care facilities, correctional facilities, and schools, WBS offers valuable insights into the health status of vulnerable groups and facilitates timely interventions. A small study in nursing homes in Spain in 2021 found 5 to 19 days of lead time for detecting SARS-CoV-2 RNA in sewage before spotting the first clinical cases (36). Similarly, a Canadian study from 2024 observed lead time of WBS signals in the majority of long-term care facilities (37).

# Pandemic and emerging disease preparedness

WBS has a potential for strengthening preparedness against emerging infectious diseases and known pathogens. A flexible WBS system, capable of integrating new tests and adapting population coverage and sampling frequency, can play a critical role in timely outbreak detection.

* **Early warning, outbreak detection and containment:** In the situation of a new pandemic or emerging disease, WBS can contribute to early warning signals to support containment in an alert phase. Studies from several U.S. states and the Netherlands demonstrated that wastewater surveillance of mpox provided early identification of high-infection areas in the absence of clinical testing, enabling timely public health interventions (38, 39). In 2022, following a confirmed paralytic polio case in Rockland County, the state of New York implemented wastewater surveillance which helped to detect poliovirus in samples across multiple counties and emphasised the need for vaccination campaigns (40, 41).
* **Monitoring of trends and mitigation:** During a pandemic, WBS can be useful to track disease spread and support mitigation. Following highly pathogenic avian influenza H5N1 outbreaks at poultry and dairy cattle farms in the U.S., enhanced H5N1 testing was implemented in wastewater samples from treatment plants across multiple states. This provided a tool to support geographical delineation of the outbreak and results could largely be confirmed with data from other surveillance systems (42-44).
* **Point of entry surveillance:** Testing of wastewater at points of entry into a country can be useful to track introductions of a pathogen or variant of interest. During the COVID-19 pandemic, aircraft wastewater monitoring in New York City, USA, (45) and Darwin, Australia, (46) among others were used as a complementary early warning system for detecting SARS-CoV-2 variants of concern. At Italy’s largest airport in Rome, mpox virus was quickly added to WBS after the emergence of mpox in 2022 (47).

1. Challenges and considerations in wastewater surveillance

WBS programmes should consider several factors at the design stage to ensure such programmes support public health needs and provide useful data. Integrating WBS with traditional surveillance systems is crucial, as WBS data need to be calibrated, contextualised and interpreted in relation to other epidemiological data. Balancing the financial and logistical costs against public health benefits, ensuring legal and regulatory compliance, and addressing privacy and ethical concerns are also key considerations. Resource requirements, including cost for sustainable and representative sampling and logistics should be considered. In this context, the economy of scale may be an important factor if multiple tests can provide more informative data from the same wastewater samples. WBS programmes should be under the oversight of ethics boards to avoid misuse of sample and data sources.

Challenges for implementing WBS programmes include harmonisation and standardisation of sampling and laboratory methods which are key to producing good-quality surveillance data. Establishing guidelines, harmonising methods and participating in external quality assessments to enhance data comparability are vital. WBS samples can often be complex, and validated methods are required to ensure reliable identification of specific pathogens amidst contaminants. For novel pathogen detection, combining PCR methods with metagenomic sequencing can enhance pathogen identification, although detecting low-abundance species and reconstructing entire genomes from complex wastewater samples remains challenging. Data must be interpreted together with other surveillance data and additional factors like population composition and meteorological or seasonal conditions. WBS data should be calibrated using other available surveillance data, such as prevalence studies, and analytical methods for assessing trends need to be robust and reliable to improve interpretation of rapid changes in the data. Shedding and limits of detection are pathogen specific and need to be established. Moreover, biomarker concentrations may vary during disease progression and may also be impacted by external factors such as population size fluctuations, wastewater treatment, and environmental factors like rain or drought, affecting detection accuracy and data interpretation.

The diverse range of actors and stakeholders necessitates cross-sectoral coordination and clear assignment of roles for effective public health action. Dedicated national coordination structures may help foster mutual understanding and enhance collaboration and responsiveness across sectors.

1. Proposed concept for integrating WBS into EU-level surveillance

# General ECDC position

ECDC acknowledges the pioneering initiatives of the European Commission and other stakeholders setting up WBS for broad public health use and the rapid development in the field in recent years. Changes in EU legislation will make wastewater sampling for multiple purposes mandatory in EU countries. Sustainable and representative sampling systems are being set up in the Member States that can be used for public health purposes. EU and global initiatives to improve and standardise sampling methods and analytical tools are ongoing. A rapid increase of evidence from the scientific literature indicates that WBS can provide useful data for public health decision making and action. ECDC therefore proposes that WBS should be integrated as complementary surveillance pillar at EU-level in order to define relevant surveillance objectives and standards. As the agency in charge of EU-level infectious disease surveillance, threat detection, assessment and communication, ECDC is well positioned to lead the consolidation, further development and coordination of national WBS systems for EU-wide use with the aim to address data gaps and limitations in current surveillance systems. Over the years, ECDC has evaluated and integrated various surveillance systems and data sources into EU-level surveillance, as exemplified by the indicator-based surveillance previously carried out by dedicated surveillance networks, genomic typing, etc. Furthermore, the Regulation on Serious Cross Border Threats to Health mandates ECDC to develop surveillance standards that encompass the full range of EU-level surveillance activities. Integration of WBS into infectious disease surveillance at ECDC should follow the procedure applied in previous integrations of surveillance systems at ECDC.

Public health needs and specific objectives should be the main drivers for integrating WBS for public health at EU level, and significant coordination and support will be needed to ensure sufficient data quality and public health impact.

# Formation of ECDC WBS Laboratory Network

ECDC proposes to form a WBS laboratory network of officially nominated national experts for WBS following the ECDC Coordinating Competent Body structure (CCB) (48). National WBS representatives including National Focal Points should represent the national public health sector and be linked to the environmental national competent body as outlined in the revised Urban Wastewater Treatment Directive. The role of the network will be overall coordination of wastewater activities for public health, sharing of experiences and best practices, agreeing on interpretation criteria and best public health use of WBS data, identification of methodological or scientific gaps, ensuring flexibility of the WBS system in case new laboratory targets need to be included in outbreak situations in the EU/EEA, stimulating timely and complete data reporting etc. Coordination with other EC services will be required to ensure such a network is well-embedded in the European context of similar networks for other WBS sectors.

# Laboratory support activities

Laboratory support activities will be provided to the WBS laboratory network following standard ECDC procedures. This support will be needs based but could include for example external quality assessments (EQA), training, reference material distribution, reference services, method harmonisation, and development of standard procedures. Laboratory support activities involving the planned super-site sentinel network procured by HERA and JRC could be considered, but would need to follow agreed procedures and be coordinated with the European Commission.

# Stakeholder groups for review of subjects proposed for WBS

For each new pathogen proposed for routine EU-level WBS, ECDC will organise consultations with Member State stakeholders to critically review the state of the art in relation to proposed objectives, operational aspects such as clinical validation, interpretation criteria and integration into standard surveillance outputs etc. ECDC will take stock of efforts made to review WBS approaches for public health use, including outcomes from specific work packages in Joint Action EU-WISH. The stakeholder group will include Member State representatives with a strong background in WBS who are using this type of data for surveillance and public health decision making at national level.

# Inclusion of WBS data in surveillance standards

In line with Regulation (EU) 2022/2371, ECDC will develop surveillance standards including specific surveillance objectives, surveillance methods, basic surveillance system descriptors, indicators to be monitored, mandatory key variables, the minimum national reporting completeness required for each key variable to enable meaningful data analysis at the Union level. Whenever relevant ECDC will propose WBS as a surveillance data source and engage the relevant disease networks accordingly. WBS will be an integral part of surveillance standards for achieving the various surveillance objectives of a given pathogen. Furthermore, Member State compliance to such standards will be monitored and reported to the Commission and Health Security Committee on an annual basis.

# Options for EU-level data sharing

WBS data should be reported from Member State competent bodies for public health and several options for data sharing are possible. As part of the consultation process of this concept paper, ECDC will identify the most suitable option for data sharing and analysis.

The UWWTD requires, a common portal for data submission needs to be created and accompanied with reporting protocols and guidance for Member States. Centralised data collection can be performed outside ECDC or using existing ECDC systems. Using the ECDC EpiPulse platform for submission of infectious disease surveillance data allows reporting of structured indicator based-data as well as ad hoc event-based data. Wherever possible, data collection should be done through automated procedures to receive results timely and efficiently. Double reporting should be avoided (Once Only Principle).

# Data analysis, assessment and regular scientific outputs

ECDC will set up pipelines for management, analysis, integration, and visualisation of WBS data. Relevant statistical algorithms for trend analysis and alert will be used. The key principle for analysis is that the WBS data should be interpreted in the context of other relevant available clinical and epidemiological information. Results from integrated analysis will be included and communicated in the standard ECDC outputs, dashboards and assessments.

1. Selection Criteria for EU-Level WBS Targets

To guide assessment of candidate pathogens or health determinants and their suitability for routine WBS and integration into EU-level surveillance, ECDC considers two main criteria (49, 50).

* Public health usefulness at EU-level (‘information for action’);
* Analytical and operational feasibility for WBS.

Public health considerations should govern the inception and definition of WBS for public health programmes and include aspects such as WBS data increasing the sensitivity of the surveillance system for a pathogen/disease. Thereby complementary WBS systems can improve epidemiological trend monitoring, the ability to detect rare or emerging diseases, early outbreak detection, or tracking the emergence and spread of pathogen variants or genetic determinants. As such, WBS programs should fill gaps in or improve existing surveillance programmes of a given pathogen/disease. ECDC will assess how and to what level WBS data can complement other surveillance data collected, e.g. by expanding the population under surveillance, improving timeliness of early warnings, enhancing interpretations of other data streams, or helping to determine relevant public health actions and providing triggers for taking such actions.

Analytical and operational feasibility for WBS includes aspects such as evidence that biomarkers are sufficiently stable and unambiguously detectable in wastewater, agreed methods for sampling, concentration, and detection of the candidate pathogen, a validated approach to epidemiological use that has been calibrated to public health outcomes of interest in relevant populations, and data standardisation and comparability between sampling sites. This may include identifying knowledge gaps and research in current methodology and approaches that need to be addressed before a target can be considered.

As outlined in section 3, the public health usefulness and the analytical and operational feasibility have been demonstrated for a number of pathogens including SARS-CoV-2, Influenza, Poliovirus etc. Further consultations are needed before recommending targets for EU-level surveillance and these consultations will follow the process outlined in section 5.4.

While not strictly affecting the selection of WBS targets, other existing (global) efforts and procedures of WBS of a target should be taken into consideration when planning for the integration of EU-level surveillance at ECDC to avoid double reporting (Once Only Principle).

Any WBS system should be designed to be flexible and rapidly adapt in response to urgent threats. In instances were novel target pathogens or health determinants need to be addressed due to a significant emerging threat, less rigid criteria may be applied.

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