RAPID RESPONSE REPORT

RAPID DATA COLLECTION AND ANALYSIS AT THE START OF A NEW OUTBREAK

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
DGS	Directorate General of Health
ECDC	European Centre for Disease Prevention and Control
EU	European Union
GP	General Practitioner
HERA	Health Emergency and Response Authority
RAG	Risk Assessment Group
RCT	Randomized Controlled Trial
RMG	Risk Management Group
WHO	World Health Organization

RECOMMENDATIONS



TO THE MINISTERS OF HEALTH AND THE INTERMINISTERIAL CONFERENCE PUBLIC HEALTH, THE BELGIAN FEDERAL PUBLIC SERVICE HEALTH, SCIENSANO, THE REGIONAL DEPARTMENTS OF HEALTH, THE RISK ASSESSMENT GROUP (RAG) AND THE RISK MANAGEMENT GROUP (RMG)

We recommend that the RAG/RMG should develop a common procedure for standardized and rapid data collection and analysis in all regions in Belgium that would be triggered (and discontinued when appropriate) by the RAG/RMG in case of a new outbreak or variant of relevance for public health.

The steps covered in the procedure are:

1. developing a preliminary case definition based on the available information;
2. informing all relevant healthcare providers of the obligatory reporting using this first case definition;
3. seamlessly collecting and cleaning data of all cases through the existing legal framework of obligatory reporting of specific infectious diseases;
4. pooling the data at Sciensano for analysis of the disease characteristics and response to the treatments tried in these first cases, in order to refine the case definition and provide feedback on key epidemiological or clinical characteristics of the novel pathogen or variant to the RAG/RMG for public health decision-making;
5. the RAG/RMG should provide rapid feedback to the infectiologists, healthcare providers and triallists on the response to treatments tried and on the need to continue complete reporting of cases.



TO THE EUROPEAN COMMISSION HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA), THE DG SANTE, THE DG RTD, THE EMERGENCY TASK FORCE (ETF) OF THE EUROPEAN MEDICINES AGENCY, THE EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC) AND THE MEMBER STATES

We recommend that the European Commission should develop, in collaboration with the Member States, a common procedure, reporting format and IT system to facilitate the rapid and systematic data collection and analysis at ECDC, to be triggered in case of a new outbreak or variant of relevance for EU public health.

The goal should be to rapidly inform public health decision makers, the healthcare providers, the EMA ETF and the Subgroup of the HERA Board to help set up appropriate clinical trials in the EU based on

1. a better characterization of the infection and a refinement of the case definition;
2. a first documentation of the initial response to treatments and interventions tried in cases and case series.

Research agenda

Infectious diseases are a part of the broader framework of chemical, biological, radionuclear, and/or explosive (CBRNe) risks and are often handled together (e.g. in KCE report no 374). Swift and efficient data collection and (risk) analysis is also needed in the broader context of CBRNe causes that can lead to disease outbreaks. This is applicable at both national and European levels. Expanding the scope of ECDC fits into this framework. Further study of efficient data collection and (risk) analysis is indicated in consultation with the actors involved, which may differ from those discussed in this report.

ABSTRACT



BACKGROUND

At the start of an outbreak of a new infectious disease or the emergence of a new variant infectiologists have to manage and treat their patients while the disease is still being characterized. A systematic and rapid data collection and analysis of the disease characteristics in the first 100 cases could help refine the case definition. Moreover, integrating a feedback loop towards the infectiologists with the outcomes of treatments or other interventions used in the first cases (or case series) could be informative for healthcare professionals and policy makers involved and for the set-up of the first clinical trials.



METHODS

Key informants directly involved in the process (e.g. infectiologists, policy advisors) in Belgium, as well as key informants of ECDC, experts of the CoMeCT project (TCB and CCB), and experts involved in mandatory reporting systems in France, Denmark, and Norway were consulted. Consultations were done via videoconferencing, face-to-face meetings or email. Selected European countries with a centralized mandatory reporting approach were studied. Moreover, information was gathered on these mandatory reporting systems from grey literature and key documents, and available scientific literature was consulted. We consulted key reports and frameworks to gather information on ECDC and WHO.



RESULTS

The existing legal framework of the mandatory reporting of specific infectious diseases (i.e. notifiable diseases) to the regional health inspectors (province/region) was identified as the ideal tool for such rapid data collection during the early phase of an outbreak of public health relevance. In Belgium, the trigger to activate the system could be the existing Risk Assessment Group (RAG) and/or Risk Management Group (RMG) mechanism at the federal level, with support from the regional (defederated) level.

The bottleneck identified in the current system is the speed of data collection, processing and analysis, which is hampered by the decentralized nature of the system that is in place in Belgium. Briefly, clinicians and laboratories report cases to the provinces within the regions in a format that differs by region. Reporting may not always be complete. These data are then pooled for analysis at the federal level by Sciensano.

Data are then transferred from Sciensano to the European Centre for Disease Control (ECDC) for a pooled analysis and feedback at the European Union (EU) level. Also the speed of these processes could be increased to meet the demands for a rapid analysis in case of a public health emergency.



DISCUSSION

Rapid data collection and analyses at the start of a new outbreak or the emergence of a new variant is possible within the existing legal framework. Improvements in the processes and the speed for the data collection and analysis requires a collaboration between the regional and federal level in Belgium. In addition, a rapid feedback loop to the clinicians is required so they can adapt the patient management based on the collected findings and remain motivated to continue the full reporting of cases.

Ideally, data should be aligned with and immediately transferred to the European Centre for Disease Control (ECDC) for a rapid pooled analysis and feedback at the European Union (EU) level to inform the public health decision-makers, to guide clinicians in their management of the first patients and to inform the EU platform clinical trials.

REPORT

1 PROBLEM STATEMENT

Pandemics caused by new or re-emerging pathogens (e.g. SARS-CoV-2) pose a serious threat to global health and require a rapid, strong and coordinated response as they have the potential to affect global health security faster than ever before. [1] In case of a new outbreak, patients and the natural course of the disease (including outcomes) need to be characterized as soon as possible. Often (re)new(ed) infectious disease (i.e. 'Disease X')[a] [2] emerges with a small number of cases, and a case definition could be formulated based on data of the first 100 cases (patients). An accelerated nosological description would enable policymakers to take action and the rapid development of clinical trials.[3]

Obstacles such as incomplete or delayed description of patients, comorbidities confounding clinical pictures and case definitions wrongly attributed, were noted in previous outbreaks. [4] Often repeated rounds of data collection and laboratory investigations were needed. Literature states that time could be saved and implementation of control measures hastened when case definitions are based on precise medical observations, implementing initial comprehensive data collection, including environmental, social and behavioral information; and involving local informants. At the same time, communication and feedback loops are needed towards the providers of data.

At the beginning of the past pandemic, and each time a new variant emerged, infectious disease specialists played a crucial role in observing and registering data on the first 100 cases by identifying (infected) patients, characterizing the disease, and gathering response on interventions tried. However, infectiologists felt the need for a more rapid feedback on the collected data and in particular the treatment response collected based on aggregated data. The process was perceived as slow, rigid, and lacking transparency. For example, the infectiologists stated "At the moment we had resources to register and investigate something, we were bound to a formal research protocol. We could start the registration only after tackling the procedures, which took too much time. By that time, we were already in the 2nd-3rd wave of COVID-19. In the meantime, and specifically for medication, there is an extreme pressure to use just about anything. Such as, in the example of COVID-19, the use of chloroquine without any rational reasoning. If a therapy is used, at least the outcome data should be collected".

The infectiologists perceived the processes for data collection and analysis as inflexible and not suited to the emergency situation (e.g. an ethics committee approval and informed consent is needed while resources are limited), there were few platforms to share data, and there were issues with regard to the privacy regulations. The issue was discussed at multiple occasions during the meetings of the Task Force Therapeutics Viral Diseases. This report is a follow-up activity of these discussions.

The infectious disease specialists asked the Federal Health Care Knowledge Centre (KCE) to evaluate how these early data collection and analysis processes could be more rapid, flexible and transparent in order to manage the patients more appropriately, to inform the setting-up of clinical trials and to provide directions for policymakers.

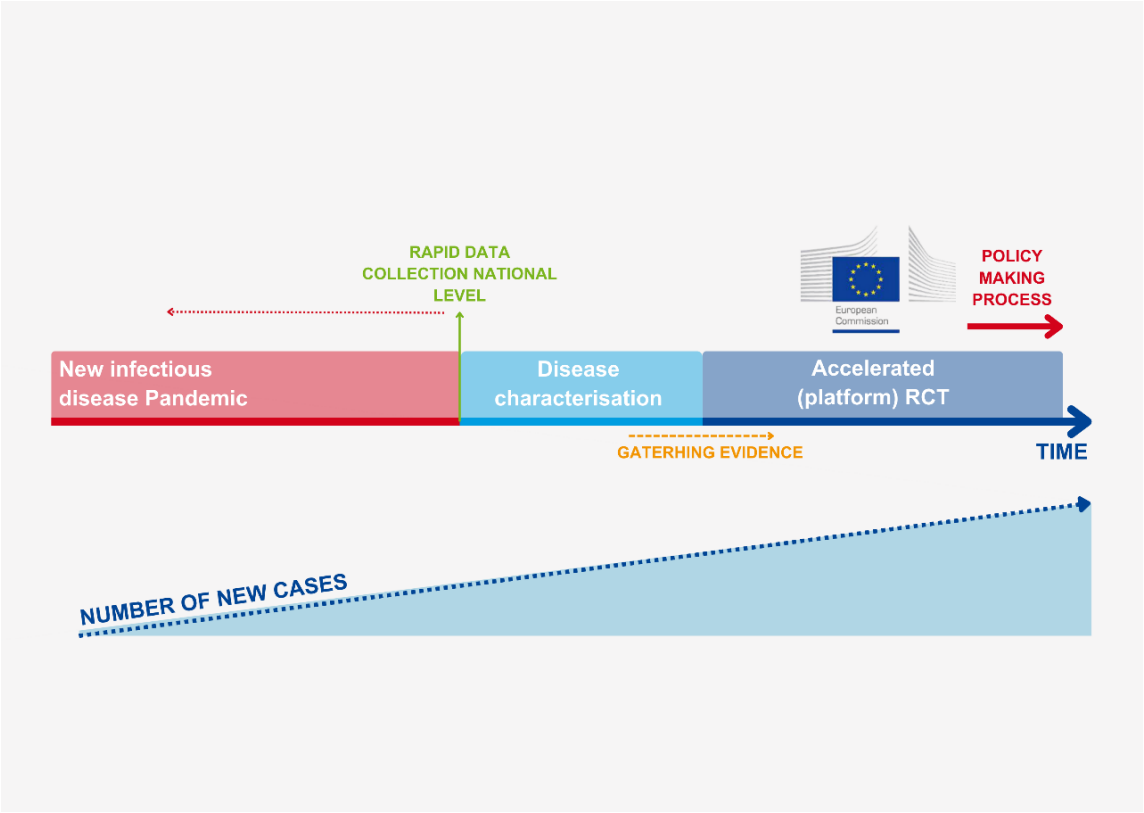
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[a] Disease X: a term to represent a hypothetical, unknown pathogen that could cause a serious international epidemic or pandemic

2 RESEARCH QUESTIONS AND METHODS

In the aftermath of COVID-19 several initiatives were undertaken to speed-up data gathering at different moments throughout **the pandemic timeline** (see Figure 1). At the start of a new emerging infectious disease outbreak the number of infected cases increases steadily and, in the event of a (re)new(ed) pathogen, there is no case definition available. Rapid data collection initiated at national level, which can be transferred to European and global organizations for surveillance, is key. These data are essential for disease characterisation, case definition and perhaps the first hints of response to the treatments tried. Afterwards, these and data from other sources can be used to gather evidence and initiate accelerated (platform) randomized controlled trials (RCT's) to enhance the policy making process.

Figure 1 – Pandemic timeline and the collection of data



Multiple hurdles and limitations on the **gathering of evidence to inform and run national RCTs and/or (platform) RCTs have been reported for** COVID-19. [5-7] Consequently, several options were suggested that may facilitate the process of data collection and the setting-up of clinical trials during an emergency situation. These suggestions include, among others:

- the use of preapproved template protocols which entails agreements on sharing data between regions and authorizations;
- the use of uniform, clear templates in a reusable format to compare data;
- the identification of relevant data beforehand;
- a stable location to publish data;
- the setting-up of licensing agreements on the reuse of data;
- the creation of structures and partnerships that facilitate prioritization of clinical research;
- simplification of clinical trial delivery;
- development of digital models and procedures for data collection and sharing;
- development of a mechanism to rapidly leverage pandemic funding and to connect EU funding with national funding;

- investments in clinical trial networks, platform trials, and master protocols;
- and the setting-up of globally connected clinical trial networks essential to respond more effectively to future infectious diseases outbreaks.

Due to the need for structured, cross-border rapid-response research infrastructures, the concept of **warm-based clinical trial networks** in Europe has been proposed. Warm-based networks allow Europe to act swiftly during health crises by utilizing prepared infrastructure and partnerships, which ultimately accelerates research and improves public health responses during pandemics and other emergencies. These networks should establish facilities, data management systems, regulatory approvals, and partnerships, which allow them to conduct trials more efficiently when a new health threat arises. Networks span multiple countries within the EU, fostering cross-border collaboration and enabling a unified response to health threats, which is particularly valuable for rare diseases and pandemics. They are designed to activate quickly in the face of new or resurgent pathogens. Researchers can immediately begin trials to test vaccines, treatments, or diagnostics without delays associated with setting up new trial infrastructure. They can remain in "warm" mode, prepared for rapid activation during health crises. The COVID-19 pandemic underscored the value of these networks, leading to additional funding and new networks. Some examples of these are (and more have been announced):

- PREPARE (Platform for European Preparedness Against Re-emerging Epidemics) [8] initiated in 2014 following the H1N1 influenza pandemic in 2009, supporting rapid research responses to infectious disease outbreaks.
- REMAP-CAP (Randomized Embedded Multifactorial Adaptive Platform for Community-Acquired Pneumonia) [9], initiated in 2016 as a global initiative to study treatments for severe community-acquired pneumonia. During COVID-19, REMAP-CAP quickly pivoted to study treatments specific to COVID-19 patients.
- VACCELERATE[10], initiated in 2021, as a European network specifically for COVID-19 vaccine trials, aiming to accelerate vaccine research through rapid collaboration and data sharing among EU countries.
- ECRAID[b] (European Clinical Research Alliance for Infectious Diseases) [11], initiated in 2019 with the aim of creating a permanent clinical research network in Europe. It focuses on building the infrastructure needed for the rapid start-up of trials on infectious diseases, including bot epidemic and endemic pathogens.
- EU-RESPONSE[c] [12]: European Research and Preparedness Network for Pandemics and Emerging Infectious Diseases) initiated in 2020, as a European hospital network capable of providing rapid research responses to infectious disease outbreaks (https://eu-response.eu)

To serve the EU's commitment to clinical trial robustness, transparency, harmonization, **CoMeCT** (Coordination Mechanism for Cohorts and Trials) [13] was established as a project by the European Union (Horizon Europe programme, No 101136531). It is a project lead by the Norwegian Institute for Public Health with several of the above clinical research networks as partners. It is a coordination mechanism that fosters collaboration between these clinical research networks and stakeholders in this ecosystem. It wants to strengthen Europe's clinical research preparedness and response to infectious disease outbreaks with epidemic potential. It facilitates strategic and scientific coordination of adaptive platform trials through the Trial Coordination Board (**TCB**) and cohort studies through the Cohort Coordination Board (**CCB**). The TCB is supported by the Joint Access Advisory Mechanism (**JAAM**), which provides a solid scientific assessment of the most promising candidate treatments through an independent panel of experts.

The clinical trials in Europe were regulated under the Clinical Trials Regulation (EU) No 536/2014 [14], until January 31 2023. From this date on, the clinical trials are initiated under the EU Clinical

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[b] The ECRAID-Base project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No. 965313.

[c] EU-RESPONSE is a 5-year project that includes two broad European Adaptive Platform Trials, DisCoVeRy and EU-SolidAct.

Trials Information System (CTIS)[d]. Since then, all new clinical trial applications in the EU have to be submitted via CTIS.

During COVID-19, in order to rapidly collect (observational) data, some existing registries were (slightly) modified and adjusted to the new pathogen e.g. the registry of the Extracorporeal Life Support Organization. At the World Health Organization (WHO), COVID-19 data i.e. 'one health data' was collected through the **One Health partnership**[e]. [7] Data from agencies was gathered in a widely used global database about the pandemic which could be consulted by relevant organizations and governments. However, the challenge of these registries is that data received from different places are not yet harmonized, limiting data comparability. Moreover, the system lacks flexibility (to add new variables related to an unknown pathogen), so data relevance can be limited. The registry also depends heavily on tha way data is documented and the frequency at which it is shared frequency by the data providers. Also, the data should be published at a stable location, the data format should be reusable and others should be licensed to reuse the data. ECDC has a similar structure in place with certain variables to be collected which can be adjusted ad hoc (e.g. for MPOX)(see below).

More recently a subgroup of the Health Emergency and Response Authority (HERA) Board[f] [15] was established to identify and prioritise candidate treatments, to create and maintain warm-based trials and strategic cohorts and to foster alignment of funding options between EU and national funding for public health emergencies.

These EU initiatives, initiated during COVID-19 or as a response to it, are very valuable but do not answer the requests of the infectiologists for a more rapid data collection and analysis on the first 100 cases of a new outbreak or variant, to allow them to better manage their first patients. Indeed, this rapid and systematic early data collection could feed nicely into the established EU initiatives. There are currently some overlaps between the goals of the HERA Board Subgroup on Clinical Trials with the JAAM in CoMeCT.

The scope of this project only covers the so-called first 100 cases of a new outbreak considered of public health relevance and the (mandatory) systems that allow for this systematic and rapid data collection and analysis, as visualized in Figure 1.

Therefore the following research questions were formulated:

1. In case of a new and unknown outbreak in Belgium, how can all necessary data on the first 100 cases most efficiently be collected, shared and analysed to characterise the outbreak and refine the case definition?
2. How can anecdotal responses to the interventions tried in these first 100 cases be rapidly gathered and used to inform the setup of clinical trials.

To answer these questions, we consulted key informants directly involved in the process at different governmental levels in Belgium such as infectiologists and policymakers. Key informants of ECDC, the experts of CoMeCT (TCB and CCB) and experts involved in mandatory reporting systems in France, Denmark, and Norway were also consulted. Consultations were done via videoconferencing, face-to-face meetings or email. A number of countries were selected to provide examples of mandatory reporting systems in countries where a more centralized approach is employed. We contacted France, Norway and Denmark to verify the gathered information from grey and scientific literature. We gathered information on these mandatory reporting systems in key documents and available scientific literature. We consulted key reports

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[d] The Clinical Trials Information System (CTIS) supports the flow of information between clinical trial sponsors, European Union (EU) Member States, European Economic Area (EEA) countries and the European Commission. CTIS went live with a searchable public website on 31 January 2022. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system

[e] The **One Health partners** come from a variety of sectors, including public health, animal health, agriculture, and environmental conservation. Together, they address complex health issues like zoonotic diseases, antimicrobial resistance, and the health impacts of climate change, working collaboratively across disciplines to ensure that human, animal, and environmental health are all protected.

[f] https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/hera-board_en

and frameworks to gather information on ECDC and WHO. If deemed necessary, corresponding legislation was consulted.

3 MANDATORY REPORTING AND SURVEILLANCE SYSTEMS

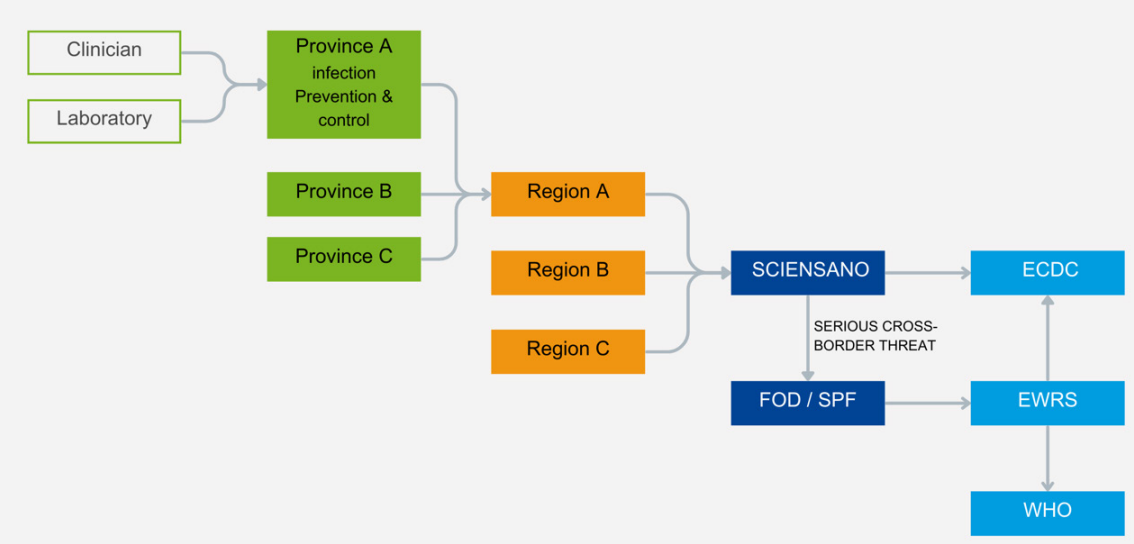
3.1 Situation at the level of EU Member States

In this chapter, we will provide a description of the mandatory reporting system in Belgium and give some examples of mandatory reporting systems in other European countries where a more centralized approach is employed. We will describe their aim, legal base, and if available provide some evaluation information. The countries (Portugal, Norway, The Netherlands, Denmark, Sweden, France) were selected during a team meeting based on the availability of scientific literature and/or contact details to verify the extracted information during expert consultation. The description of the reporting systems will focus on their possible use for the purpose of our project.

3.1.1 In Belgium

In Belgium, the system for mandatory infectious disease surveillance operates through a collaboration between national and regional health authorities (i.e. Flanders, the Brussels Capital Region, the Walloon region and the German speaking region), underpinned by both federal and regional legal frameworks. [16-19] The regions have enacted decrees, such as the Flanders' Decree on Preventive Health Policy (Decreet betreffende het preventieve gezondheidsbeleid) [20], outlining region-specific requirements for infectious disease monitoring and the transmission of critical health information (see Box 1). These decrees mandate information on symptoms, diagnostic results, and treatment outcomes as required data points to ensure comprehensive monitoring. This decentralized approach means that certain notifiable infectious diseases (e.g., Legionella, tuberculosis) are reported directly to the province (e.g. Antwerp, Belgium) and transferred to the region (e.g. Flanders, Belgium) where the case occurs (Figure 2).

Figure 2 – Reporting data from the clinician and lab towards ECDC and WHO



This enables each region to assess the public health risk and determine appropriate local measures. Each federated health authority is responsible for the monitoring of 40+ notifiable infectious diseases. Although the list of notifiable diseases and the collected data may vary across the different regions, mostly the same pathogens are collected (e.g. polio, dengue) as well as the data reported i.e. start date of symptoms, results, provided therapy, and outcomes. [16, 17, 20]. Clinicians or microbiologists are required by law to report either suspected or laboratory-confirmed cases to the regional Health Authorities for infection prevention and control measures (see Figure 2). The National Public Health Institute (Sciensano) [21](see Box 1), outlined in federal legislation, oversees epidemiological data and conducts infectious disease surveillance on behalf of Belgium at an international level by collaborating closely with the SPF, ECDC [22] and the WHO regional level. For information on ECDC, WHO and EWRS we refer to section 4.2 and 4.3, and chapter 5 in this report.

Box 1 – Overview of federal and federated supporting agencies and regulatory bodies of Belgium

Federated agencies or bodies with their corresponding decree:

Doctors and laboratories are obligated to report certain infectious diseases to the appropriate government agencies, using a specific template:

- The Department for Care – Departement Zorg for Flanders[23]. Decreet betreffende het preventieve gezondheidsbeleid [16, 20]
- The administration of the Common Community Commission – Vivalis for Brussels [16, 24]
- The Agency for a Life of Quality – Agency pour une Vie de Qualité for Wallonia[17, 25]
- Hygiene Inspection of the Ministry of the German-speaking Community – Hygieneinspektion van Ministerium der Deutschsprachigen Gemeinschaft for the German-speaking Community [19, 26]

Federal supporting agencies in providing data and expertise for informed decision making:

Sciensano: the National Public Health Institute (Sciensano) can provide support with registering the notification of the infectious disease, the source research and contact tracing, and analyzing the data collected during these processes. It can also provide advice to the competent authorities to prevent or limit the further spread of the infectious disease. Monitoring patients and spread of diseases, data on the occurrence of infectious diseases is also collected nationally and internationally to be able to further map out and monitor the epidemiological situation of certain infectious diseases. Sciensano provides support to federal entities in case of outbreaks, transmits infectious disease epidemiology to international institutes (e.g. ECDC, WHO), performs health threat detection through the Risk Assessment Group (RAG) and makes recommendations to health authorities regarding the implementation of measures to combat and prevent infectious diseases. Sciensano is also responsible for the development of expertise in diagnosis and sub-analyses of infectious diseases. Its Healthdata.be platform provides a technical infrastructure for the collection of registries, using a pseudonymized national registry number. The platform also facilitates automated data extraction (e.g. from clinical laboratories) and the linkage of registries.

FOD-SPF (the Federal Service for Public Health): they maintain a registry of the minimal hospital dataset used for the financing of hospitals. They were also responsible for the hospital surge capacity management plan during the COVID-19 pandemic.

RIZIV-INAMI (Institute for Disease and Disability Insurance) collects reimbursement data on treatments and diagnostics (e.g., Hep C, HIV). This data can be used for epidemiological purposes.

There are approximately **40 National Reference Centres for Human Microbiology (NRCHMs)** across Belgium, which are reference laboratories with increased expertise and capacity for testing of different pathogens. They usually perform secondary analyses. The network is coordinated by Sciensano.

A law to establish **a Health Data Agency (HDA)** [27] was approved in March 2023 by the Chamber of Representatives. The aim of the HDA is to facilitate access to health data, in particular for secondary use.

Federal regulatory bodies:

Risk Assessment Group (RAG) [28]**:** an advisory group with both permanent members (comprising the federal and federated health authorities) and national experts according to Disease Groups (airborne, vector-borne, foodborne, sexually transmitted, etc.) across the fields of microbiology, epidemiology, primary and secondary clinical care and public health. Sciensano coordinates the group and invites external experts to provide scientific input when developing risk assessments. Sciensano is responsible for continuous health threat detection and initiates a risk assessment through the RAG to provide general management advice to the Risk Management Group (RMG).

Risk Management Group (RMG): in the event of a public health threat, the RMG decides on the measures to reduce the risk for the Belgian population. It is a permanent group composed

of representatives of Belgium's health authorities and coordinated by the National Focal Point for the International Health Regulations of the Federal Public Health Service. FOD, DepZorg, AVIQ, VIVALIS - RAG coordinator provides input of risk assessments and epidemiologic evaluation of global recommendations.

The **Interministerial Conference (IMC) on Public Health** brings together 9 Ministers of Health and has the last word on political decisions relating to proposals made by health authorities. A fragmented public health mandate and policy decision-making process undermines collaborative crisis management and long-term action plans for the eradication of infectious diseases.

Sciensano performs these duties by coordinating and maintaining multiple surveillance systems to cover the epidemiological follow-up of pathogens relevant for national public health. These networks include, among others, wastewater-based epidemiology, clinical laboratories, National Reference Centers, general practitioners and hospitals. As the subnational Health Authorities are responsible for infection prevention and control, they coordinate the Mandatory Notification of Infectious Diseases for these activities: e.g. contact tracing, quarantine, isolation and vaccination or immunization policies. The data collected within the scope of these activities for mandatory notifiable pathogens are collected at the level of each region and transferred towards Sciensano to bolster the epidemiological surveillance. However, as each regional Health Authority has their own legal mandate for mandatory notifiable diseases, there are differences across the subnational entities both in the platforms that are utilized for data collection, in the pathogens which are obligatory to report per region, in the data that is collected per pathogen, and in the frequency at which the data is reported to Sciensano at the national level. An overview of the common registries used for infectious diseases surveillance is provided in Box 2.

Box 2 – Surveillance systems for infectious diseases

Sentinel network of clinical laboratories (Epilabo): collects diagnostic data as well as basic demographic patient information, date, and type of test for 40+ pathogens across Belgium.

Sentinel network of general practitioners (GP): collects clinical and microbiological data among patients presenting with acute respiratory infection or influenza-like illness at the GP. Microbiological samples are taken among a subset of patients for multiplex PCR testing (16 respiratory pathogens) at the National Reference Centre for Influenza. These results are coupled with the clinical data.

Sentinel network of hospitals for severe acute respiratory infection (SARI): collects clinical and microbiological data among all SARI patients admitted to one of the six participating hospitals. Microbiological samples are taken among a subset of patients for multiplex PCR testing (16 respiratory pathogens) at the National Reference Centre for Influenza. These results are coupled with the clinical data.

GP Barometer: collects data (semi-automatically) on the number of weekly GP consultations for influenza-like illness.

Registry of notifiable infectious diseases: Physicians are required by law to notify these infectious disease cases to the federated subnational Health Authorities for contact tracing and infection prevention and control activities.

Vaccine registries (VaccinNet, eVax, VacciCard): These registries are coordinated and maintained by the subnational Health Authorities.

Network of National Reference Centres (NRCs): Coordinated by Sciensano. Each NRC reports basic demographic patient information and specific microbiological results (antigen, PCR, sequencing, etc) for their respective pathogen.

Next to that, there are many **disease or context specific monitoring systems** such as HIV-AIDS Reference Laboratories, PediSurv (network for pediatricians and GPs), TekenNet, MEMO+ (exotic tiger mosquito), etc.

During the COVID-19 pandemic, several surveillance platforms were established, including for SARS-CoV-2 laboratory test results (including negative test results, genomic variants), pharmacy test results, prescription data, wastewater surveillance, clinical surveillance of

hospitalized COVID-19 patients, surge capacity surveillance of hospitalized COVID-19 patients, national nursing home surveillance of COVID-19 cases, vaccination registry Vaccinnet+, contact tracing, etc.

Within the **healthdata.be infrastructure**, it was possible to automatically extract data from clinical laboratories through the Laboratory Information Management System (LIMS) and link these datasets to other national registries such as vaccination, registry of healthcare actors (CoBRHA), reimbursement data (IMA-AIM), socio-economic and mortality registries (Statbel).

- **Common Base Registry for HealthCare Actor (CoBRHA):** This database provides data on healthcare workers and their healthcare organization, to follow up incidence rates per type of healthcare worker.
- **StatBel**: national individual-level data on socio-economic status, mortality and cause of death (e.g. infections)
- **IMA-AIM:** reimbursement data, allowing to calculate incidence rates among people with comorbidities

Although Sciensano coordinates multiple epidemiological surveillance systems, these networks have been developed for the epidemiological monitoring of known pathogens. Therefore they are not always ideal for the ad-hoc rapid collection of both laboratory and clinical data during an outbreak involving a new pathogen or variant. The Registry of Mandatory Notifiable Diseases does have the legal framework to collect clinical data of infectious cases caused by novel pathogens, but due to the 'split' responsibilities (decentralized approach) inconsistencies in data collection occur. Moreover, communication and management is more complex, complicating efforts towards a unified national public health response, especially when newly emerging pathogens arise for which data collection needs to suddenly be developed and harmonized. A decentralized approach also implies that each region uses its own infrastructure, databases, and notification systems, resulting in varying reporting standards and procedures (see Box 1 lawful base)[29]. This lack of harmonization can impede the swift sharing of critical health data, which is essential for prompt decision-making. For instance, differences in IT systems and data formats can delay data integration at the national level, impacting the quality and completeness of data transferred to Sciensano and Belgium's reports to international bodies. Although Sciensano coordinates with regional authorities, there is no legal structure or governance. The regional Health Authorities, via the provinces, do have the mandate to collect personal data for infection prevention and control measures, including for novel pathogens or variants. This provided the legal framework to allow the subnational entities to collect information during the SARS-CoV-2 and Mpox pandemics. However, there remains a gap in coordination work to harmonize data for evidence-based analysis and recommendations. These regulatory disparities can complicate coordination and lead to jurisdictional overlaps or gaps, affecting the surveillance system's efficiency.

- During the early stages of COVID-19, delays were observed in collecting and sharing data on risk factors and case definitions, underscoring the system's need for quicker, harmonized responses in public health emergencies. Moreover, the surveillance system operates under both federal and regional legal frameworks, which sometimes differ in terms of reporting requirements and procedural mandates. While federal laws govern national reporting obligations in the case of a Public Health Emergency, regional decrees (e.g., Flanders' preventive health policy decree) outline specific requirements within each community for the mandatory reporting of notifiable diseases.
- During the Mpox 2022 pandemic, Sciensano coordinated with subnational Health Authorities to align data collection with the ECDC requirements for reporting through the indicator-based surveillance system TESSy (see section 4.3). Although the infrastructures differ at subnational level, there was a coordinated inter-federal initiative to produce harmonized data collection and weekly reporting of Belgium's cases to facilitate national epidemiological surveillance and reporting by Sciensano.

Moreover, communication channels do not just differ across entities, but also depending on the context (peace-time vs. public health emergencies)[30]. In case of an outbreak that crosses regional borders, the inter-federal RMG decides how to communicate to GP's but the subnational Health Authorities retain the responsibility for communication, as they also have the pre-existing communication channels in place to increase awareness and communicate to GP's for their peace-time infection prevention and control activities. During public health emergencies the federal Health Authority has the mandate to communicate to the general population; however during peacetime this is limited to the hospital setting and airports (Saniport). A decentralized approach requires input from various bodies, including the RAG and RMG. This can make decision-making lengthy and complex, with inter-ministerial meetings (IMC) required to agree on communication strategies and public health actions. This bureaucratic layering can slow down response times during rapidly evolving health crises. These complexities in terms of operational roles and mandates, including the definition of when the country moves towards a federal public health emergency phase, require clarification within the inter-federal Generic Preparedness Plan and Viral Outbreak Plans (see recommendation).

Belgium, was the first European Union and European Economic Area (EU/EEA) country, to be evaluated by the Public Health Emergency Preparedness Assessments (**PHEPA**) at ECDC[g].[32] An overview of the main conclusions and recommendations for Belgium are listed in Box 3.

Box 3 – Main bullets from PHEPA on Belgium

Main bullets from PHEPA on Belgium

The report [32] concluded that: "Although Belgium is a complex country due to the federated structure, the strong collaborative working observed between the federal level and the federated entities provides a firm base for future enhancement of the prevention, preparedness and response planning function in public health. Although DG Preparedness and Response is a new department in the FPS Health, Food Chain Safety and Environment, the general response structure to threats as they emerge, led through the National Crisis Centre (NCCN) is well established. In addition, the federated entities have come to similar conclusions on the approach to be adopted in planning for and responding to crisis. This should enable DG Preparedness and Response, as it further develops and finalizes its General Preparedness Plan and operational plans, to align and link with these pre-existing structures to provide a robust framework for the management of public health threats." Some recommendations that were made are related to:

- Laboratory surge capacity and the development of the be.Prepared platform for effective automated reporting of laboratory and epidemiological data, with integration of genomic data, data from clinical laboratories and NRCs, reuse of the national registry number to bolster the mandatory notification of mandatory notification diseases.
- Expanding the ARI-ILI Sentinel Surveillance network by a) including more GPs in the electronic health record-based surveillance of acute respiratory infections in primary care, b) expand the ILI sentinel surveillance network in long-term care facilities for the elderly, by increasing the participation rate in underrepresented regions, and c) improve hospital-based surveillance of SARI, including through the extraction of data from electronic health records and automation of the reporting process.
- Expanding capacities to assess pandemic threats by a) defining protocols for investigation of new pathogens and/or variants in coordination with subnational entities; b) setting up cooperation and data-sharing agreements with regional vaccination registries, considering the national and regional legal frameworks; and c) formalizing and documenting agreements and partnerships with academia and other stakeholders to strengthen modelling and forecasting capabilities.
- Distinguish between the strategic approach (General Preparedness Plan)[30] and the operational documents (Viral Outbreak Plan), and how these relate to each other and apply between the federal level and the federated entities. The General Preparedness Plan could retain its strategic scope and the federal operational plans could provide the necessary

g Article 8 of the Regulation (EU) 2022/2371 on Serious Cross-Border Threats to Health [31].

federal aspect linking to the federated entities. However, it is also necessary to ensure that the various plans of the federated entities take the federal plans account and are consistent with them.

- Continue the development of tools to ensure monitoring of supply and estimating demand, taking into account the reporting requirements that would be applicable in case of a public health emergency. The relevant tools should allow to collect information for all the relevant types of products that fall under the definition of Medical Counter Measure (MCM). Existing provisions under the general preparedness plan or relevant policies should be revised to reflect current and future initiatives in this field. Coordination between the regional and federal level should be clarified in terms of reporting relating to the monitoring of supply and estimated demand.
- Establish a formalized One Health governance for prevention, preparedness and response to zoonotic and environmental health threats involving the different sectors and authorities from the federal and regional levels.
- Finalize the modules on zoonotic diseases and vector transmission currently under development as part of the Viral Outbreak Plan complementing the General Preparedness Plan. Refer to the relevant existing plans relating to climate change and environmental health in the General Preparedness Plan and ensure alignment by detailing how these plans relate to one another.
- Identify high-priority Multidrug-resistant Organisms and clarify processes for notification. Determination of high-priority Multidrug-resistant Organisms is needed to clarify which Multidrug-resistant Organisms require immediate action by Infection Prevention and Control personnel and outbreak support teams, now that 'Multidrug-resistant Organism outbreaks' are on the federated entities' lists of notifiable diseases.

Based on these previous experiences it has become clear that although there are legal frameworks to collect data, the underlying structures and Public Sector Governance are not well aligned to respond rapidly for the development of new harmonized data collections to gather key points of evidence for novel pathogens or variants for which there is a paucity of scientific evidence.

3.1.2 In Portugal

In Portugal, the mandatory National Epidemiological Surveillance System / 'Sistema Nacional De Vigiláncia Epidemiologica (**SINAVE**[h]) is an application system designed to dematerialize the notification process for notifiable diseases, including those resistant to antimicrobials. [33] It automatically interacts with healthcare-related infection surveillance systems. SINAVE provides healthcare professionals, including physicians and laboratories, with an electronic form to record notifications and sends information and alerts to local and regional health delegates (registration of notifications and epidemiological surveys). It also provides surveillance and statistical information to the Directorate-General of Health (DGS), which coordinates the surveillance system and tracks trends in communicable diseases. They report to ECDC via TESSy. The main benefits are the improvement in quality of data recorded in notifications and epidemiological surveys since the computerized recording is done by the individuals themselves; the privacy of patient information; the increase in the number of notifications and epidemiological surveys for mandatory notifiable diseases; and the reduction of time in information transfer. [33]

In November 2020, the DGS introduced BI SINAVE, a new system for data treatment, analysis and communication which was more dynamic in the context of the COVID-19 pandemic. [34] BI SINAVE has a greater capacity to process information contained in databases such as SINAVE Lab and SINAVE Med and maximizes the usefulness of the information from various complementary sources (Trace-COVID and National User Register). [34]

h https://www.spms.min-saude.pt/2020/07/sinave-2/

SINAVE's data quality was investigated through the data characteristic 'completeness' for Meningococcal Disease in Northern Portugal between 2020-2022 [35], as well as for COVID-19 surveillance [36].

- It is mandatory in Portugal to notify suspected cases for Meningococcal Disease in SINAVE to implement effective control measures through epidemiological investigation, risk assessment and community intervention. [35] The results confirmed under-reporting of and incomplete reporting of Meningococcal Disease. The authors concluded there is a need to strengthen the improvement of data quality for SINAVE (e.g. comparing results for other diseases) to improve public health actions.
- COVID-19 laboratory notifications, clinical notifications, and epidemiological investigation questionnaires were electronically submitted to SINAVE by laboratories, clinicians, and public health professionals, respectively, as mandated by law. [36] The authors saw that after January 2021, clinical notification and epidemiological investigation questionnaires were submitted in a small proportion of laboratory-confirmed cases, varying by age and region. They indicate that due to the large number of COVID-19 cases, public health services may have adopted other registry strategies contributing to the abandonment of official notification. The authors concluded that regular evaluation of pandemic surveillance systems' completeness is necessary to inform surveillance improvements and procedures considering dynamic objectives, usefulness, acceptability, and simplicity.

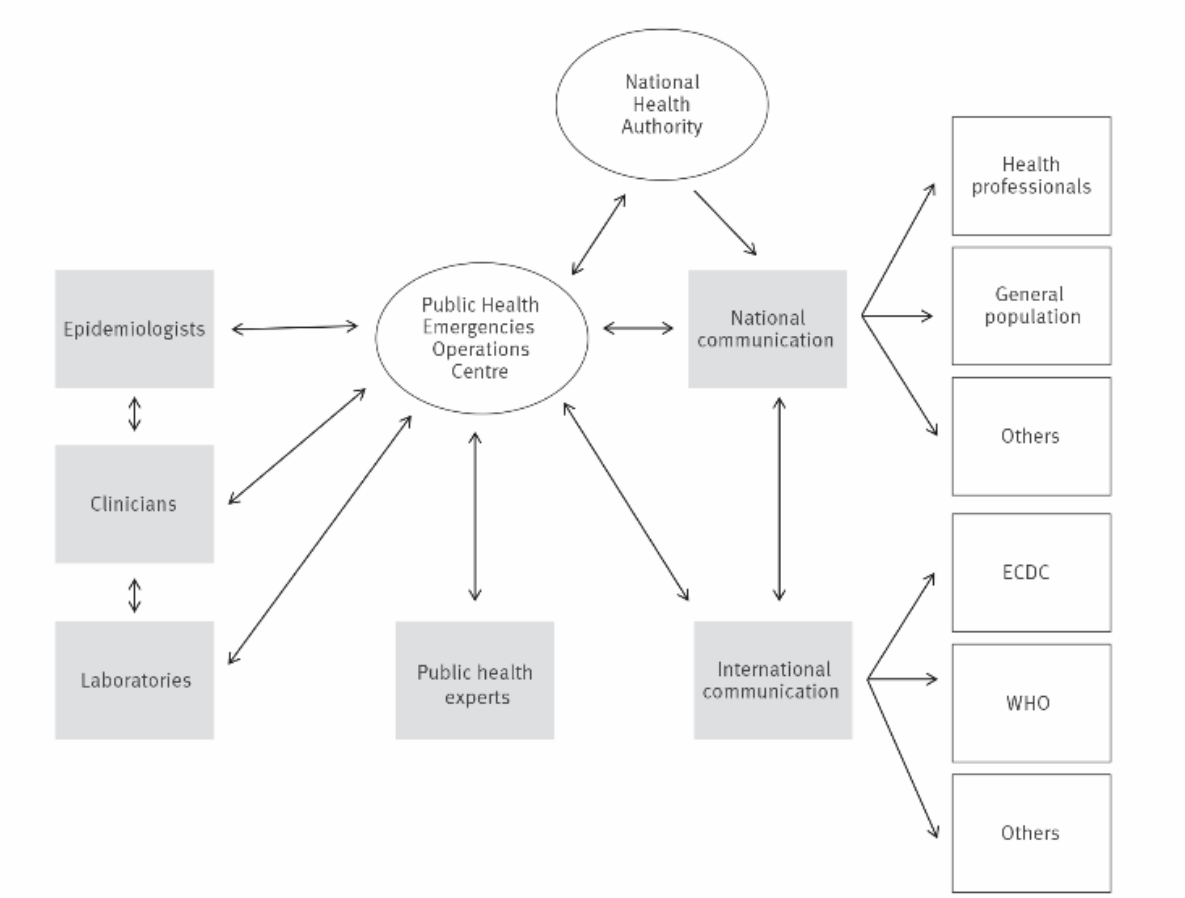
There are also retrospective studies available conducting retrospective assessments of data quality on data in SINAVE collected on COVID-19. [37] Some attempt to improve quality through data linkage of COVID-19 cases surveillance systems (SINAVE) and mortality systems (SICO). [38] The interoperability of SICO and SINAVE databases would potentially improve available Health Information Systems and improve available information to decision-making.

In 2022, this system also allowed the Portuguese Task Force to rapidly respond to **an outbreak of severe acute hepatitis of unknown etiology** in children in Portugal (see Figure 3). [39] The experts of the Task Force came from various disciplines: clinicians, laboratory experts, epidemiologists, public health experts and national and international communication. Moreover, Portugal adopted the ECDC and WHO case definition and recommendations (as outlined in TESSy). [40] According to those, urgent hospital admission was required for children up to 16 years of age with clinical manifestations suggestive of acute hepatitis or nonspecific clinical manifestations such as abdominal pain, nausea and vomiting, diarrhea, jaundice, with more than 1 week of evolution and significant prostration. Moreover, laboratory analyses were requested according to ECDC/WHO guidelines. [40] Probable cases were required to be promptly notified to the DGS. As part of the notification, clinicians encountering a patient who met the probable case definition had to complete an online form. This way, information about the cases was collected to understand the epidemiological link, as the form included information on each case like e.g. location of the case, educational center or contact with other sick children. This made it easier for the Task Force to discern potential epidemiological links among the cases. The online form was created and subsequently integrated into **SINAVE**. The Task Force reinforced identification of retrospective cases among pediatricians through the Portuguese Society of Pediatrics. All cases were discussed and validated within the Task Force to evaluate if the criteria for probable case were met and to ensure that microbiological findings of all cases were confirmed at the National Reference Laboratory. These discussions between clinicians, epidemiologists and laboratory experts ensured complementary laboratory investigation, including adenovirus genotyping when isolates were available. Patients with acute hepatitis that did not meet the probable case criteria were followed-up. Additionally, the Task Force maintained a regular appraisal of the epidemiological situation using national and international routine alerts networks (see Figure 3). They held regular meetings to follow the evolution of the outbreak, adjusting the frequency as needed (from weekly to monthly). This allowed them to understand any potential seasonality of the alert while ensuring timely detection of severe cases. The Task Force recommended prevention and control measures for suspected or probable cases in healthcare facilities, complying with established rules for infection control by the National Program for the Prevention and Control of Infections and Antimicrobial Resistance (PPCIRA)[i]. The Task Force communicated to the media and to healthcare professionals on protective measures to share the latest scientific evidence available in a transparent and approachable language, to avoid panic. The Task Force

[i] https://www.sns.gov.pt/institucional/programas-de-saude-prioritarios/programa-nacional-para-a-prevencao-e-controlo-de-infecoes-e-de-resistencia-aos-antimicrobianos-2/

in Portugal may have contributed to an increased awareness among clinicians, enabling early detection and prompt management of the outbreak

Figure 3 – Description of the Portuguese Task Force and communication (retrieved from Grau-Pujol et al. 2023[39])



3.1.3 In Norway

The Norwegian Institute of Public Health (NIPH) is the national institute for infectious disease control. Its responsibilities include monitoring, receiving notifications and reports, contact tracing, vaccine preparedness, advising, information and research. The NIPH is responsible for the notification system for communicable diseases.

During a crisis, the Directorate of Health (DoH[j]) (Helsedirektoratet) is responsible for the national coordination of health system actions, as well as heading the National Health Preparedness Commission regarding biological threats (HPCB), which is an advisory body. [41] The Norwegian Institute of Public Health (NIPH) (Folkehelseinstituttet) is represented in the HPCB and is responsible for the secretariat-functions with regard to infection control. Beside this, the NIPH[k] is expected to: "contribute with monitoring, give advice on infection control measures and communication of risks, support the DoH and the Preparedness-Commission in developing and implementing communication strategies. Together with the DoH, NIPH's role is thus to support and facilitate the activities of the preparedness commission and other relevant public bodies, and participate in the continuous preparedness with communication of information/advice". [41] Note that some of the responsibilities of NIPH are being shifted to the Norwegian Medicines Agency.

A surveillance system for communicable diseases from NIPH, is in place since 1975 i.e. the Norwegian Surveillance System for Communicable Diseases (**MSIS**). [42] MSIS gathers individual-level data on various infectious diseases (around 70) such as airborne, foodborne, zoonotic [43], and sexually transmitted infections. [44] The system ensures data protection by using national identifiers and allows for linkage of data for research purposes i.e. researchers, health personnel, students, etc. can apply for access to data and may receive data in the form of tables for health monitoring or research for an explicitly declared purpose. [42] It helps guide public health responses and policies related to disease outbreaks. The MSIS operates under Norwegian legal frameworks and is updated annually. It also supports ongoing pandemic surveillance, including COVID-19.

The data flow includes (1) data collection from hospitals, clinics, and laboratories, (2) data transmission to MSIS, (3) data storage in the national database, (4) analysis by experts at the NIPH, (5) report generation for authorities, and (6) feedback loop to healthcare providers, students, researchers, etc.

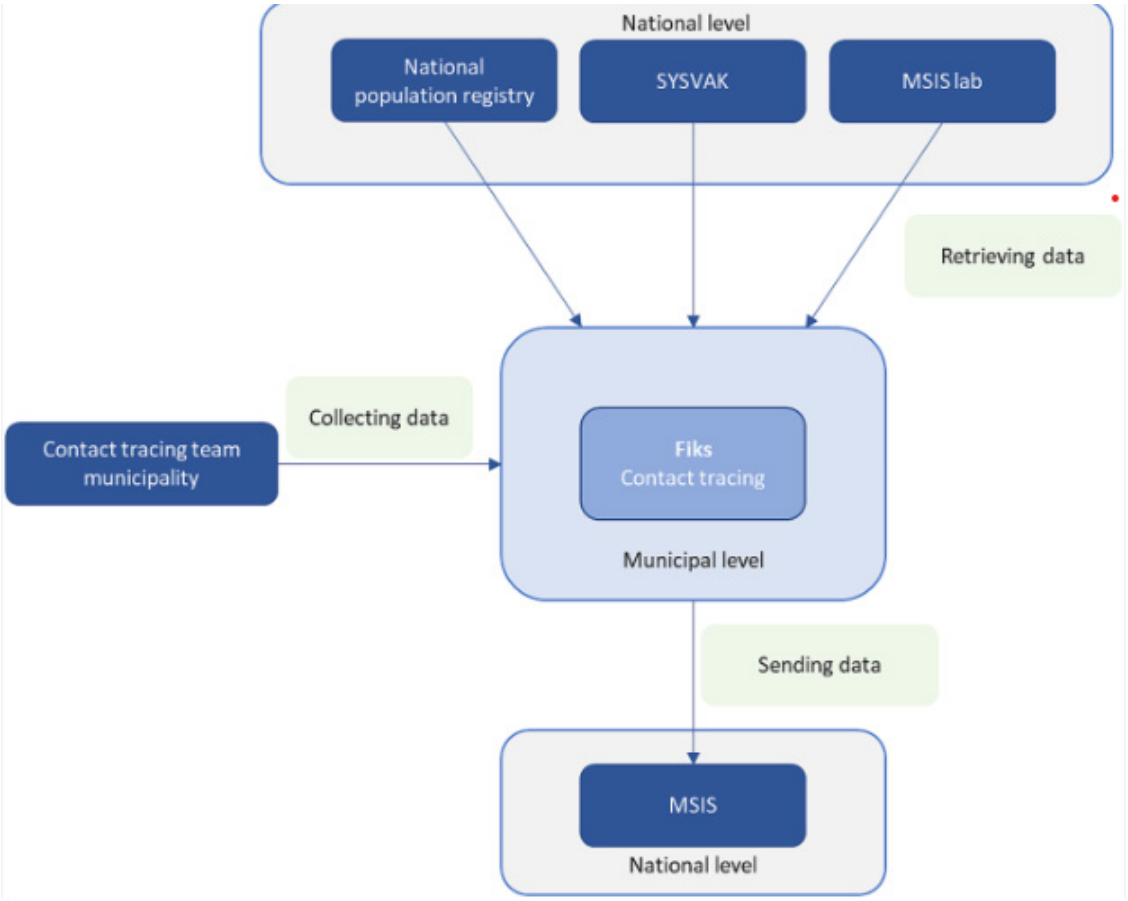
MSIS proved to be robust enough to maintain its function during the COVID-19 epidemic because extensive work to upgrade the system was started before the pandemic and intensified during its course. [45] The system was flexible enough to accommodate the inclusion of a new disease in the list of notifiable diseases even in a context of strained resources.[44, 45] There were some challenges relating to data quality, data sensitivity, reduced representativeness, reduced completeness, etc. especially in the primary healthcare. [45] Reporting timelines, however, were improved overall, which can be attributed to the introduction of new reporting tools and improved user support. For example, during the COVID-19 pandemic, contact tracing tool (FiksCT) was used (see Figure 4). [46] This tool is based on DHIS2, an open source, web-based platform and was used to register positive individuals and follow-up contacts. FiksCT data was linked to the MSIS, the National Population Register (FREG), and the Norwegian Vaccine Registry (SYSVAK) using unique identification numbers. The DoH and NIPH work jointly to provide an effective and coordinated effort towards the prevention and control of infectious diseases. The agencies also ensure that public health data is collected, stored, and shared in compliance with applicable laws and regulations. [47] The completeness of local contact tracing data can be improved by enabling integration with established national registers. In addition, providing the option to submit local data to the national registers could ease workload and reduce the need to collect duplicate data. [46]. Norway is part of One Health.

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j https://www.helsedirektoratet.no/english

k https://www.fhi.no/en/

Figure 4 – Overview of the FIKS contact tracing tool, based on DHIS2 platform, and integration with national registers (figure retrieved from Meijerink et al. 2024[46]).



3.1.4 In The Netherlands

Osiris[l] is a generic information system used by the RIVM[m] ('Rijksinstituut voor Volksgezondheid en Milieu) and various cooperating organizations to register and manage data collections. The first application was the registration of mandatory notifiable diseases i.e. Osiris AIZ (including notifiable infectious diseases (AIZ), Dutch Tuberculosis Register (NTR), virological charts, and source detection of foodborne outbreaks (NVWA)) by the Municipal Health Services ('Gemeentelijke Gezondheidsdienst' or GGDs) and RIVM. After that, other programs and projects started using the Osiris framework. Osiris contains information about the patient (including year of birth, hospitalization, vaccination status), the infectious disease (including symptoms, diagnostics performed, results of diagnostics) and the possible site and mode of infection. Mandatory reporting of infectious diseases exists since 1865. The RIVM database contains information on notifiable infectious diseases from 1988 onwards. **Osiris** is used by healthcare professionals, such as general practitioners and laboratories, to report notifiable infectious diseases (around 50) to the GGDs ('Gemeentelijke Gezondheidsdienst'). There are reporting standards available[n]. The GGD's gather the information (which represent the Dutch population) and transfer it to Osiris, managed by RIVM. The RIVM is legally regulated under the Public Health Act ('Wet publieke gezondheid'). [48] [49] and collects, analyses and interprets data on infectious diseases by conducting field and laboratory research. When a notification is made, the GGD traces the source of the infection and investigates whether contacts of the patient are at risk of infection. The GGD can take measures to protect contacts and prevent the disease from spreading. The GGD then reports the notifiable infectious disease to the Centre for Infectious

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l https://osiris.rivm.nl/#:~:text=OSIRIS%20is%20een%20generiek%20informatie systeem,registeren%20en%20beheren%20van%20gegevensverzamelingen.

m https://www.rivm.nl/surveillance-van-infectieziekten/meldingsplichtige-infectieziekten

n https://www.rivm.nl/documenten/meldingsnorm-voor-meldingsplichtige-ziekten

Diseases ('Centrum Infectieziektenbestrijding' - CIb), which is part of the RIVM, in a pseudonymized form. The CIb uses this information to monitor trends and occurrences of these diseases, develop and evaluate national policies (such as the National Vaccination Program), and implement control measures at a national level if needed. If there's a threat of an international outbreak, the CIb assesses whether the report needs to be forwarded to the WHO. Information on notifiable infectious diseases in the Netherlands is then reported to ECDC.

3.1.5 In Sweden

The **SmiNet**[o] notification system is developed, owned and financed jointly by the Public Health Agency of Sweden ('Folkhälsomyndigheten') and the country's infection control units. [50] All of Sweden's infection control units are connected to the system, as are the microbiological laboratories and thousands of healthcare units. The Public Health Agency of Sweden is responsible for the operation, support, management and development of the system.

According to the Infection Control Act (2004:168) [51] and Infection Control Ordinance (2004:255) [52], treating physicians, physicians at laboratories performing microbiological diagnostics, the person responsible for such laboratories, and physicians performing autopsies, who suspect or confirm cases of a generally hazardous disease or other notifiable disease, must notify this without delay to the infectious disease physician in the region where the notifying physician has his or her professional activities and to the Public Health Agency of Sweden. Notifications are most easily submitted via SmiNet. SmiNet is the system used jointly by all the country's infectious disease physicians, infection control units and the Public Health Agency of Sweden to monitor the 60 or so diseases that are notifiable under the Infection Control Act.[51] The system facilitates the work of handling notified cases, outbreaks and other infection control matters. The case definitions for notification under the Infection Control Act are listed on the website[53] to specify the criteria that must be met to report a case under the legislation. Infection control sheets are also available. [54] The Public Health Agency of Sweden provides general information on both notifiable and non-notifiable communicable diseases[p]. This information is primarily aimed at regions, municipalities and other relevant actors while private individuals are referred to the 1177 Healthcare Guide or to their nearest healthcare center.

By doctors and laboratories in Sweden reporting cases of infectious diseases to SmiNet, the regional infection control units and the Public Health Agency of Sweden can follow the epidemiological situation of various diseases both locally and nationally. This allows outbreaks to be detected early and measures to be taken. [55]

3.1.6 In Denmark

In Denmark, the surveillance of infectious diseases is managed by the Statens Serum Institut (SSI), and entails 1) a laboratory reporting system and 2) a mandatory notification system for individual cases.

1. The laboratory reporting system is based on the **Danish Microbiology Database (MiBa)**, established in 2010, which is a country-wide automatically updated database of microbiological test results. [56]
2. The mandatory notification system for individual cases is based on **MIS** ('Meldesystem for Infektionssygdomme'). The system requires that healthcare professionals report specific diseases to help monitor, control, and prevent outbreaks.

MiBa has four primary purposes i.e. patient treatment, national IT projects, infection control, and surveillance. [56]

- For infection control there is MiBAlert [57], an automatically updated alarm function in regional electronic health records. MiBAlert shows the healthcare professionals whether the patient has been infected by certain microorganisms, e.g., resistant bacteria, and therefore requires specialised treatment and isolation upon admission.
- For surveillance, it lays the foundation for the national surveillance of infectious diseases, including surveillance of antimicrobial resistance. Automation of MiBa-based surveillance will

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[o] https://www.folkhalsomyndigheten.se/sminet/om-sminet/

[p] https://www.folkhalsomyndigheten.se/smittskydd-beredskap/smittsamma-sjukdomar/

gradually expand in the coming years. COVID-19 surveillance and the Healthcare-associated Infections Database (HAIBA) are examples of surveillance systems based on MiBa data.

The mandatory notification system based on MIS entails two types of mandatory notifications i.e. the immediate (urgent) notifications for severe cases, such as outbreaks, or diseases like tuberculosis and viral hepatitis, for which reports must be made immediately by phone in addition to the electronic form [58], and the routine individual notifications which are less urgent and must be reported within a set timeframe through filling out and uploading an electronic form.

The regulatory framework for the national surveillance in Denmark is The National Board of Health Statutory Order (BEK nr 1260 af 27/10/2023 (Gældende)) on Notifications of Infectious Diseases etc., [58] The system also feeds into broader European and global surveillance networks like the ECDC and WHO for international preparedness.

3.1.7 In France

In France, a number of interconnected systems are in place for the purpose of monitoring infectious diseases (specific notifiable diseases) [59]. The mandatory reporting system for infectious diseases is called the 'Système de Déclaration Obligatoire' (**DO**). A total of 38 notifiable diseases are identified, 36 of which are classified as infectious, next to HIV and TB. Data is received through a secure web portal. Currently Santé Publique France (SPF) is working to develop a similar portal for the 36 remaining infectious diseases. [60] It is the responsibility of any physician (whether a doctor or a biologist), who has made a diagnosis of a notifiable disease to send a notification form specific to the disease in question to the Agence Régionale de Santé (ARS) without delay (also available by phone). The ARS will then forward the form to SPF. Regarding HIV and TB, the declarations made via the online digital portal are transmitted in such a way that the confidentiality of the patient's identity is ensured. [61] The objective of the current system is to implement local and national measures designed to prevent epidemics, and also to launch inquiries with the aim of identifying the source of the contamination.

The syndromic surveillance system SurSaUD® (2004) (Surveillance sanitaire des urgences et des décès) is broader and focuses on real-time monitoring of health trends across the general population. It collects data (including electronic death certification data and mortality data from the civil registry services of municipalities) from various sources like emergency departments (OSCOUR® (Organisation de la surveillance coordonnée des urgences)), sentinel networks, and healthcare professionals (in large cities) (*SOS Médecins France*) to detect potential outbreaks based on symptoms (syndromes) rather than confirmed diagnoses. This system is particularly useful for early detection of emerging diseases or other health threats. Santé Publique France employs SurSaUD® enabling the provision of real-time insights into the general population's health status. [59]

The Réseau Sentinelles is a network established in 1984 and which is being actively engaged in the monitoring of a number of epidemics.[62] The organization comprises over 1 300 volunteer general practitioners and paediatricians based in various locations throughout France (also coverage of smaller cities). Réseau Sentinelles is involved in the detection of epidemics, the construction of databases for the purposes of health monitoring and research, and the implementation of clinical and epidemiological studies. Since 2020, in response to COVID-19, the network has expanded its monitoring activities to encompass acute respiratory infections, including various respiratory viruses. The data collected by the Réseau Sentinelles are included in the national-level surveillance coordinated by SPF, which is the main contact for ECDC.

Next to these, there are also other voluntary-based surveillance networks in France, e.g. for pertussis, severe invasive bacterial diseases, etc. These rely on data sent by clinicians (intensivists, pediatricians, etc.) or microbiologists. Also health insurance data is used to produce surveillance indicators for other infectious diseases such as Lyme and hepatitis. Moreover, there is a network of 43 funded national reference laboratories, which provide microbiological expertise and contribute to surveillance through their lab networks and activities e.g. characterization of strains, sequencing, etc. Last, there are 3 transversal programs, initiated during or right after the COVID-19 pandemic, that support specific activities: i.e. EMERGEN for increasing sequencing capacities, SUM'EAU for waste water surveillance, and ORCHIDEE which is a program funded by the EU until 2029 to explore e-health approaches, working mainly with hospital health data warehouses to produce surveillance indicators.

Key points for EU member states

In **Belgium**, a mandatory decentralized system exists to report on notifiable infectious diseases. It operates through a collaboration between national and regional authorities underpinned by both federal and regional frameworks. Each regional Health Authority has their own legal mandate for mandatory notifiable diseases. This means there are differences across the subnational entities both in the platforms that are utilized for data collection, in the pathogens which are obligatory to report per region, in the data that is collected for each pathogen, and in the frequency at which the data is reported to Sciensano at the national level. Sciensano coordinates and maintains multiple surveillance systems to cover the epidemiological follow-up of pathogens relevant for national public health. Sciensano's systems for known pathogens are not always ideal for the ad-hoc rapid collection of both laboratory and clinical data during an outbreak involving a new pathogen or variant. The Registry of Mandatory Notifiable Diseases does have the legal framework to collect clinical data of infectious cases caused by novel pathogens. Sciensano's mission is made complex due to the 'split' authorizations of a decentralized approach which implies that each region uses its own infrastructure, databases, and notification systems, resulting in varying reporting standards and procedures.

In other member states (Portugal, Norway, The Netherlands, Sweden, Denmark and France) there is a more centralized approach.

The **Portuguese** mandatory reporting application **SINAVE** automatically interacts with healthcare-related infection surveillance systems. It provides healthcare professionals, including physicians and laboratories, with an electronic form to record notifications and sends information and alerts to local and regional health delegates.

In **Norway**, the mandatory reporting system **MSIS** (introduced in 1975) ensures data protection by using national identifiers and allows for linkage of data for research purposes i.e. for researchers, health personnel, students, etc. They can apply for access to data, which they may receive in the form of tables for health monitoring or research for an explicitly declared purpose. **MSIS** was flexible enough to accommodate the inclusion of a new disease in the list of notifiable diseases even in a context of strained resources (e.g. COVID-19), but there were some challenges regarding data quality, data sensitivity, reduced representativeness, reduced completeness, etc., especially in primary healthcare.

In **The Netherlands**, the mandatory reporting system Osiris is a generic information system used by the **RIVM** and various cooperating organizations to register and manage data collections (since 1988). Osiris is used by healthcare professionals, such as general practitioners and laboratories, to report (following standards) notifiable infectious diseases to GGDs.

The mandatory **SmiNet** notification system connects all of **Sweden's** infection control units, like the microbiological laboratories and thousands of healthcare units. The Public Health Agency of Sweden is responsible for the operation, support, management and development of the system.

In **Denmark**, the surveillance of infectious diseases is managed by the Statens Serum Institut (**SSI**), and entails a mandatory laboratory reporting system (**MiBa**) for indicator-based surveillance and a mandatory notification system for individual cases (**MIS**) for event-based surveillance.

In **France**, the mandatory reporting system for infectious diseases is called DO. Next to that, there is also a syndromic surveillance system SurSaUD® which is broader and focuses on real-time monitoring of health trends across the general population. There is also a broader network for data registration among healthcare professionals i.e. Réseau Sentinelles

In Belgium and in the described member states, there is a reporting flow to ECDC.

3.2 The World Health Organization (WHO) initiatives

In this section, we will provide a non-exhaustive overview and short description of certain key frameworks, systems and structures that could be of relevance to this report. However, it is not always clear from the publicly available information to which extent these multiple initiatives and systems interact with each other, and how active they are.

3.2.1 International Health Regulation (IHR) and surveillance

The WHO early response to an outbreak is regulated by the International Health Regulation (IHR), revised in 2005 and amended in in 2014 and 2022.[63] The IHR specifies that the National IHR Focal Point of the Member needs to notify WHO within 24 hours of all events which may constitute a public health emergency of international concern.

Article 6 IHR is clear about the information that must be disclosed: it should include, where possible, case definitions, laboratory results, the source and type of the risk, the number of cases and deaths, conditions affecting the spread of the disease, and the health measures employed. The IHR also obtains rapid case based reporting of serious outbreaks in a globally standardized way such as in COVID-19. [64]

However, this information-sharing obligation is overly dependent on Members' goodwill, their ability and willingness to detect the problem and share available information in a timely matter. If the Member concerned falls short in its information-sharing obligation, the WHO has no way to force the State into being more forthcoming. [65]For example, when WHO was warned of the situation in Wuhan, China, on 31 December 2019, this was not through the expected route but by way of non-governmental actors (see Figure 1).

3.2.2 The Emergency Response Framework

The Emergency Response Framework (ERF) provides WHO staff with essential guidance on how WHO manages the assessment, grading and response to public health events and emergencies with health consequences, in support of Member States and affected communities. [66] The ERF adopts an all-hazards approach and it is therefore applicable in all acute public health events and emergencies.

3.2.3 The Global Health Observatory

The Global Health Observatory (GHO)[67] is a WHO initiative that provides access to a wide array of global health data, including health statistics, trends, and surveillance systems. Several surveillance and response systems operate under the GHO and the broader WHO framework to track various public health threats, including infectious diseases, environmental risks, and non-communicable diseases. These systems play a vital role in collecting, analyzing, and disseminating health data to support global public health decision-making**,** policy formation**, and** outbreak preparedness and response at national, regional and global levels**.** There are several surveillance and response systems managed or supported by the WHO and integrated into the GHO. One example are the disease specific systems such as Global Influenza Surveillance and Response System (GISRS)[q68] and Global TB Surveillance and Monitoring System[r], which focus on disease specific surveillance, resistance patterns, vaccine strain selection, and pandemic preparedness. Within the GHO, the reporting of public health events of international concern (e.g., infectious disease outbreaks) to the WHO is made possible by a legally binding agreement i.e. the abovementioned IHR[s].

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q https://www.who.int/data/gho/data/themes/global-influenza-virological-surveillance

r https://www.who.int/activities/tb-monitoring-and-evaluation

s The Monitoring and Evaluation Framework, signed by 196 countries including all EU MS focuses on monitoring compliance with IHR guidelines and coordinating global health emergency response. It concerns the rapid notification of WHO for new cases of public health concern and the global standardization of reporting on public health events.

3.2.4 Public Health Emergency Operations Centers (PHEOCs)t.

A PHEOC is a hub for coordinating the preparedness, response and recovery processes for public health emergencies using a multisectoral approach. [69] Effective PHEOCs can swiftly detect a broad range of public health risks by combining inputs from a range of surveillance systems (e.g. from GHO). It is a platform to streamline the flow of information and the allocation of resources needed to manage incidents.

3.2.5 Global Outbreak Alert and Response Network (GOARN)

The Global Outbreak Alert and Response Network (GOARN)[u], [70] provides international public health resources to control outbreaks and public health emergencies across the globe. It is a WHO network of over 250 technical institutions and networks globally that respond to acute public health events with the deployment of staff and resources to affected countries. Coordinated by an Operational Support Team based at the WHO headquarters in Geneva and governed by a Steering committee, they aim to deliver rapid and effective support to prevent and control infectious diseases outbreaks and public health emergencies when requested. [71] [72]

The GOARN's capacities concern health information and epidemiology, laboratory and diagnostics (e.g. deployments), case management (e.g. deployment of experts), infection prevention and control (e.g. control experts), risk communication and community engagement, strengthening and training. [71] Concerning health information and epidemiology, an example is the integrated outbreak analytics (IOA) to ensure the timely generation of consolidated and actionable evidence for decision-makers, as happened during the 2018-2020 Ebola virus disease outbreak in the Democratic Republic of the Congo. [71]

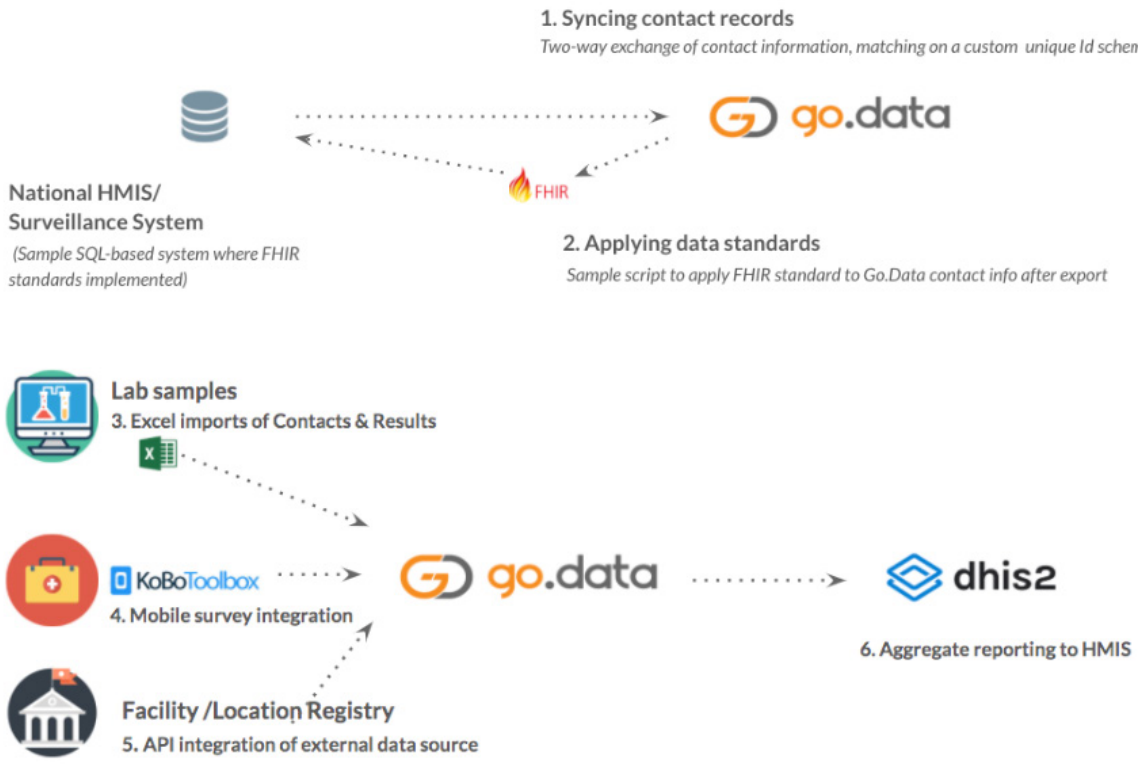
Moreover, access to real-time and representative data is critical to enable key response activities during an outbreak, regardless of its scope or severity. [71] This implies that outbreak response teams at all levels of the health care system have mechanisms in place for information management. **Go.Data** is a platform for outbreak response and contact tracing developed by WHO in collaboration with GOARN's partners. [73] Its primary purposes are to streamline and integrate data collection for cases, contacts and exposure events, and to enable visualization of the linkages between them to reveal and describe chains of transmissions. It is an outbreak investigation tool for field data collection during public health emergencies. It performs rapid data collection on early cases and contact networks and is highly flexible. The tool includes functionalities for case investigation, contact follow-up, visualization of chains of transmission including secure data exchange and is designed for flexibility in the field, to adapt to the wide range of outbreak scenarios. The tool is targeted at any outbreak responder. An example is Go.Data as a game-changer in addressing the 2022 mpox outbreak in Chile (see Box 4). [74]

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t National and international coordination hubs for emergency response.

u A global network of institutions and organizations that respond to public health emergencies, especially infectious disease outbreaks. It coordinates the rapid deployment of technical expertise, equipment, and resources to contain outbreaks like Ebola, Zika, cholera, and COVID-19.

Figure 5 – Interoperability between National Surveillance System and Go.Data



Box 4 – Go.Data as a game-changer in addressing the 2022 mpox outbreak in Chile' (retrieved from [74])

Chile's national surveillance system, Epivigila, has been crucial in managing COVID-19 notifications. However, when the first case of Mpox was reported in the country, the Epivigila system was not available for creating new notifications forms, a situation that posed some initial challenges. [74]

Faced with an escalating public health emergency, the Chilean health authorities recognized the need for a timely comprehensive response to manage the emerging threat. Within just weeks, the Ministery of Health developed a epidemiological interview form using Go.Data and provided training for response teams. This early approach proved crucial to control the outbreak. In particular, the implementation of Go.Data introduced several groundbreaking features:

1. The platform enabled precise tracking of transmission chains by incorporating relationship types, and exposure details.
2. Data was transformed into actionable insights through real-time visualization, allowing monitoring of the outbreak as it evolved.
3. Fields for gender and social name were included, demonstrating commitment to inclusive health practices.
4. Individuals' occupations were incorporated, enabling analysis of potential workplace exposures.
5. The system was integrated to vaccination and laboratory data, providing a comprehensive view of the cases.

It was seen that even with limited information, Go.Data allowed the mapping of potential transmission chains and the identification of contacts that might have been missed. Also, a visual representation of the way the virus was spreading through communities enabled more precise and effective interventions, and real-time data facilitated crucial informed decision-making in a rapidly evolving outbreak.

In conclusion, Chile's experience with Go.Data during the 2022 mpox outbreak demonstrates the vital role of adaptable digital tools in public health responses. The rapid deployment of Go.Data, paired with well-trained health workers, allowed Chile to control the outbreak effectively. This success positioned the country to better respond to future health emergencies, underscoring the importance of scalable and integrated systems in safeguarding public health.

3.2.6 Early Warning, Alert and Response (System) (EWAR(S)) and EWARS-in-a-box)

WHO states that to reduce the impact of outbreaks and public health emergencies, countries must strengthen their capacity to complete the cycle of public health emergency prevention, preparedness, response, and recovery, while reviewing and strengthening EWAR capabilities at each step. As outlined in the operational guide [75], EWAR provides an early warning of acute public health events of all-hazards [76] and connects this function to an immediate public health response based on field data collection. [75] EWAR is composed of 3 components i.e. early warning[v] (including indicator-based surveillance (IBS) and event-based surveillance (EBS), alert (verification of a signal and in case of an event, assessment and characterization of the risk, for which an alert can then be provided), and response (outbreak investigation, generic immediate control measures and/or agent specific control measures). [75] The early warning components i.e. IBS and EBS are explained in Box 5.

[v] The rapid detection of signals that may indicate potential acute public health events. Sources of early warning data may include notifications from health facilities, community members and other entities, which feed into IBS and EBS systems.

EBS is one of the core components of Early Warning for public health hazards, working together with IBS to detect potential public health events. [75] A key strength of EBS is that it can be implemented rapidly at the onset of an emergency, while IBS is patchy and not fully functioning. Initiating EBS reporting from health facilities (e.g. through hotline) and key community representatives can then be a feasible and meaningful option to start surveillance for EWAR purposes, while other surveillance activities are progressively scaled-up. While distinctions in IBS and EBS remain relevant in some settings, case and event definitions share many similarities, and both pathways may be integrated into common system for early warning.

EWARS-in-a-box [77] facilitates collection of both weekly IBS data transmission and ad hoc event reports from EBS. However, this is only accessible to devices integrated into the electronic EWAR. It should be assumed that community members do not have access to mobile phones to make reports. Therefore, any established EBS source should be facilitated to relay potential signals from community members who visit those health facilities e.g. EWARS mobile app collects data from various field settings and contains any number of reporting forms. Reporting happens in real time. Data can be aggregated or case-based.

Usually the national public health authorities lead the implementation with support from WHO and other partners. Ideally, all national surveillance systems should have an EWAR function that can rapidly detect and respond to disease outbreaks and other acute public health events. [75]

WHO itself also obtains to improve its data collection processes and implementation as seen in scientific literature towards for example the establishment of a minimum list of variables needed for outbreak investigation[3] and an evaluation (challenges and lessons learned) from investigating outbreaks in complex environments[4].

Box 5 – the early warning components of EWAR: the IBS and EBS system

Indicator-based surveillance (IBS)

IBS is the systematic and regular (weekly) reporting and collection, monitoring, analysis and interpretation of structured data (indicators) produced by defined reporting sources (e.g. health care facilities, laboratories, volunteer networks, etc.), on diseases with trends as the alert threshold. [75] IBS provides reports on cases meeting pre-defined case definitions for a maximum of 8-12 priority diseases and health conditions, as well as the associated case definition[w]. For EWAR, IBS case definitions are mostly syndromic, based on signs and symptoms that are easy to detect and do not necessarily need laboratory testing or advanced diagnostics, for which the process is more rapid e.g. '*A person with acute onset of jaundice (yellowing of whites of eyes or skin or dark urine) AND severe illness with or without fever AND the absence of any known precipitating factors*'. Community case definitions are simplified versions of syndromic case definitions that make it possible for non-medically trained people to decide if someone is a case or not e.g. '*A person with yellow eyes*'. Next to that also outbreak case definitions can be defined e.g. '*A person with acute jaundice and fever and is resident of Camp X since at least 30 October 2021'*.

Where available, case definitions issued by the national public health authorities (or equivalent) should be used for reporting from health facilities. [75] Where these are not available, the **WHO Outbreak Toolkit** [78] provides a repository of definitions for select diseases (as well as templates of line lists and data dictionary)(see section 4.2.8). [75] In the event a new and emerging disease is detected and included under EWAR IBS systems, new case definitions may need to be developed based on any available information on the epidemiology, clinical presentation and laboratory findings to date, which are reviewed periodically and adjusted as more information of a local disease or condition becomes available.

An example of signal and no signal in IBS:

- The IBS system detects one case of potential viral hemorrhagic fever (VHF). The alert threshold for VHF is one case, and a signal is generated.

[w] A case definition is a set of standard criteria that must be fulfilled to classify a person as a case of a particular disease or health condition for the purposes of surveillance and outbreak investigation. Definitions must be clear, appropriate, need to be consistently applied, and should be listed in surveillance reports to aid interpretation

- The IBS system detects 20 cases of malaria within one week. The alert threshold for malaria is based on the number of reported cases from previous years in the same season and is 32 cases for the week in question. The alert threshold is not passed; therefore, the information is reported to the EWAR system, but no signal is generated.

Event-based surveillance (EBS)

EBS is the organized collection, monitoring, assessment and interpretation of mainly unstructured ad hoc information regarding potential public health hazards, which may represent an acute risk to human health. [78] It is not based on case definitions and may detect potential public health hazards faster, can reach beyond health facilities, and can detect diseases that are not explicitly covered in the IBS system. It is based on immediate triage and immediate reporting for diseases with 1 case as the alert threshold (daily and ad-hoc). It provides real-time signals for any event of public health concern, including ad-hoc information not limited to pre-identified priority diseases and conditions, reaching beyond healthcare-centered sources. EBS systems can be restricted to defined reporting sources (e.g. health care facilities, community workers,…) and/or be open to anyone to report (e.g. phone hotlines, text message, media). They report events meeting pre-defined event definition for example 'at least five cases of severely sick persons (cannot walk anymore) with similar complaints in the same village within two weeks' or more sensitive event definitions such as 'a cluster of cases in the community'. These can be deliberately broad or tailored to detect events related to a specific threat/ongoing outbreak. It is not restricted to specific prioritized diseases or hazards, may be based on unstructured information and can include other sectors (e.g. environmental health). [78]

An example of signal and no signal in EBS:

- The EBS system detects a cluster of three unexplained deaths in a village at the centre of the emergency. The triage indicates the information has not been reported elsewhere and a cluster of deaths can potentially indicate an acute public health event. A signal is generated.
- The EBS system detects five severely injured cases from a road accident of two cars. The triage indicates the information has not been reported before, but injuries by road traffic accident do not constitute a potential acute public health event. The information does not become a signal.

3.2.7 WHO outbreak toolkit

On the WHO Outbreak Toolkit site[x] [78], epidemiologists and field investigators can find up-to-date, comprehensive tools for use in the investigation of outbreaks of infectious and non-infectious diseases and hazards. The Outbreak Toolbox covers a list of around 22 diseases, with information provided on 7 topics for each disease (see Figure 6).

The standardized data collection tools lists two disease case investigation forms for the 22 diseases. Moreover, to enhance comparability and sharing of data collected between investigation teams, locations, and time frames, there is also an **EXPOSURE case investigation form**, for situations where the disease causing the outbreak is unknown and the source or mode of transmission is suspected; and a **SYNDROME case investigation form** for situations where the disease causing the outbreak is unknown and the clinical syndrome has been identified.

x https://www.who.int/emergencies/outbreak-toolkit

Figure 6 – WHO disease outbreak toolkit



3.2.8 WHO Hub for Pandemic and Epidemic Intelligence and EIOS.

The WHO Hub for Pandemic and Epidemic Intelligence (WHO Hub) was established in Berlin in 2021 with the foundational support of the Government of the Federal Republic of Germany. The mission is to improve data, analytics and decision-making to minimize the impacts of pandemic and epidemic threats. [79] In the key achievements report of 2024 the following topics were noted for 2023: collaborative surveillance interpretation, international pathogen surveillance network (ISPN), health security partnership to strengthen surveillance in Africa (HSPA), epidemic intelligence from open sources (EIOS), and the Collaboratory. [79]

The Epidemic Intelligence from Open Sources (EIOS) focuses on early detection by Artificial Intelligence and machine-learning to identify potential outbreaks globally (early warning) using non-traditional data, including scanning publicly available data across languages and sources i.e. open source data. [80] The EIOS initiative is grounded in a long-standing partnership between WHO and the European Commission's Joint Research Centre (JRC). [80] A core objective of EIOS is the rapid identification of disease outbreaks. [80]. In January 2022, EIOS became part of the WHO Hub for Pandemic and Epidemic Intelligence.[1]

Keypoints on WHO

The WHO early response to an outbreak is regulated by the **International Health Regulation (IHR)**.

Several systems and frameworks of relevance for this report are available at WHO. Among others there are:

- The **ERF** provides WHO staff with essential guidance
- The **GHO** is a WHO initiative that provides access to a wide array of global health data, including health statistics, trends, and surveillance systems.
- A **PHEOC** is a hub for coordinating the preparedness, response and recovery processes for public health emergencies using a multisectoral approach.
- The **GOARN** provides international public health resources to control outbreaks and public health emergencies across the globe. It is a WHO network of over 250 technical institutions and networks globally that respond to acute public health events with the deployment of staff and resources to affected countries
- **Go.Data** is a platform for outbreak response and contact tracing developed by WHO in collaboration with GOARN's partners. Its primary purposes are to streamline and integrate data collection for cases, contacts and exposure events, and to enable visualization of the linkages between them to reveal and describe chains of transmissions.
- **EWAR** provides an early warning of acute public health events of all-hazards and connects this function to an immediate public health response based on field data collection. The early warning component includes indicator-based surveillance (IBS) and event-based surveillance (EBS).

- **IBS** is the systematic and regular (weekly) reporting and collection, monitoring, analysis and interpretation of structured data (indicators) produced by defined reporting sources (e.g. health care facilities, laboratories, volunteer networks, etc.), on diseases with trends as the alert threshold.
- **EBS** is the organized collection, monitoring, assessment and interpretation of mainly unstructured ad hoc information regarding potential public health hazards, which may represent an acute risk to human health.
- **EWARS-in-a-box** facilitates collection of both weekly IBS data transmission and ad hoc event reports from EBS.
- Where available, case definitions issued by the national public health authorities (or equivalent) should be used for reporting from health facilities. Where these are not available, the **WHO Outbreak Toolkit** provides a repository of definitions for select diseases.
- **EIOS** focusses on early detection by Artificial Intelligence and machine-learning to identify potential outbreaks globally (early warning) using non-traditional data, including scanning publicly available data across languages and sources i.e. open source data. EIOS is part of the **WHO Hub**, an institution to improve data, analytics and decision-making to minimize the impacts of pandemic and epidemic threats

3.3 Indicator-based and event-based surveillance at ECDC: EpiPulse cases and EpiPulse events (formerly TESSy and EPIS respectively)

EpiPulse cases (primarily focused on indicator-based surveillance and routine reporting of infectious diseases) and **EpiPulse events** (designed to support event-based surveillance and epidemic intelligence by capturing potential health threats through a range of data sources) provide two complementary surveillance approaches within the ECDC for comprehensive infectious disease monitoring across Europe. Current activities are ongoing to integrate both systems (with TESSy transitioning to 'EpiPulse Cases', alongside the already existing 'EpiPulse Events') by 2025 (see Box 6).

Box 6 – EpiPulse Cases (former TESSy) and EpiPulse Events (former EPIS)

The European Surveillance System (TESSy)[81] for indicator-based surveillance[y] is the main system used by ECDC to collect, analyze, and report data on communicable diseases across Europe. This system is currently being retired and replaced by **EpiPulse Cases**. It compiles data from EU/EEA member states' national mandatory notification systems, focusing on the systematic reporting of case-based and/or aggregate data. Data reported to TESSy includes detailed epidemiological information on nearly 60 infectious diseases and health conditions. It includes detailed information on cases of reportable diseases, detects outbreaks, monitors prevention programs, identifies risk factors, and quantifies disease burden.

The European Surveillance Portal for infectious diseases (EpiPulse) [82] for event-based surveillance[z] was launched by ECDC in 2021 and aims to strengthen the prevention and control of infectious diseases. It is an online portal for public health authorities to collect, analyze, share, and discuss infectious disease data for threat detection, monitoring, risk assessment and outbreak response. It provides epidemic intelligence and genome sequencing data. **EpiPulse Events** gathers information from diverse sources, including official reports, media, and informal channels. It includes both structured surveillance data and unstructured event reports, offering a real-time, comprehensive view of possible health threats. Used for epidemic intelligence and risk assessment, EpiPulse supports the ECDC's rapid response capabilities for emerging or re-emerging health events in Europe.

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y Tracks the occurrence of specific diseases, focusing on the incidence rate over time.

z Monitors reports of unusual health events or outbreaks from various sources.

4 CHALLENGES AND ONGOING ACTIONS AT THE EUROPEAN LEVEL

Data from EU member states reporting systems on certain notifiable diseases (i.e. those for which there is a joint surveillance, like respiratory virus [83]) are transferred from ECDC to WHO. For most diseases, however, WHO does not receive data directly from ECDC, but can use its outputs. If needed, WHO can request access to ECDC data on an ad-hoc basis. The primary legal framework governing the transfer of data on infectious diseases from the ECDC to WHO is the IHR**,** supported by specific agreements like the Memorandum of Understanding (MoU) between the ECDC and WHO (see section 4.2.1), and the EU Decision 1082/2013/EU on Serious Cross-border Threats to Health. [31] These agreements ensure that data (including ad-hoc data) is shared efficiently and legally to enhance global health security and respond to public health threats.

An important challenge for both WHO and ECDC systems to monitor trends and detect outbreaks is that they rely heavily on data reported by national surveillance systems (which are dependent of their national regulations for mandatory disease reporting and the representativeness of other surveillance systems at the level of laboratories or healthcare providers). [84]

Data from national surveillance systems follow country-specific regulations for (mandatory) disease reporting, although the EU regulation on cross-border threats to health is national law in the 27 member states. [84] Systems in countries like Norway and Portugal work well under stable conditions and for known pathogens, and show some adaptability for new threats. However, significant obstacles, such as delays in setting case definitions, limit their responsiveness. The ECDC goes beyond simply aggregating national data; it adds an EU-wide perspective, which strengthens comparability and public health response across Europe's diverse healthcare systems, languages, and data standards. [84] Differences in surveillance capacity, infrastructure, and resources across countries can impact the consistency of infectious diseases epidemiology as well as routine surveillance data reported to the ECDC, complicating cross-border coordination during health crises. Varying terminology, data sources, and IT systems further complicate harmonization. While advances have been made in analytic tools for outbreak prediction, fewer resources have been dedicated to improving data quality and timeliness in the field. During COVID-19, understanding disease spread was crucial for policymaking, but challenges arose due to the local storage of most health data and the lack of a streamlined system for international data sharing. Many agencies struggled with data sharing and lacked pre-existing agreements, reusable data templates, stable data repositories, and licensing agreements for data reuse.

In the aftermath of COVID-19, some important initiatives were undertaken such as the ECDC's 2021-2027 surveillance framework, and the strengthening of ECDC's mandate to improve rapid data collection in the event of a new outbreak. Perhaps the most important development is that by adopting the Regulation on cross-border health threats, member states have accepted that the European Commission establishes binding surveillance standards (through the implementation of Art 13 and Art 14). Surveillance standards will define data requirements (see further).

The ECDC's 2021-2027 surveillance framework[84] strengthens EU/EEA public health monitoring by enhancing national data with a supranational perspective, allowing for more standardized and comparable disease tracking across countries. Its goals include setting common standards, bolstering national capacities, and supporting budget planning for surveillance beyond crisis periods. Key actions involve revising the EU notifiable disease list, upgrading IT infrastructure, and promoting digitalization to replace outdated paper-based systems. Efforts focus on integrating molecular and genomic data with environmental and veterinary information, and leveraging new data sources such as big data and artificial intelligence, alongside electronic health records and mobile health apps. Lessons from the COVID-19 pandemic, especially around delays and data gaps, highlight the need to ensure timely, actionable insights for public health policy and practice in the EU/EEA. Some of the specific actions, relevant for this report, are outlined in Box 7.

Box 7 – Specific actions from the ECDC's 2021-2027 surveillance framework [84]

Action 2.4: Early outbreak detection and pandemic preparedness

Improve early multi-country outbreak detection and pandemic preparedness for more timely coordinated response.

Target: Integrated sentinel surveillance of respiratory viral infections, weekly or, where required, real-time laboratory surveillance of suitable outbreak-prone diseases and minimum pandemic surveillance dataset operational (2027)

Action 3.3: Effective risk communication

Systematically use EU/EEA infectious disease surveillance findings to highlight public health risks, and actively reach out to the European Commission, Member States, and media to influence policy and public awareness.

Target: EU/EEA-surveillance-derived public health risk assessments reflected in European Commission outputs and picked up by the media (2027).

Action 3.4: Open data access

Provide open access to EU/EEA infectious disease surveillance data to promote their dissemination and use for public health science and practice.

Target: Web-based surveillance data warehouse interface in place to enable customized manual download and machine-to-machine consumption of data subsets, aiming to offer findable, accessible, interoperable and reusable data in accordance with the FAIR principles (2023).

Action 4.2: Digitalized integrated national surveillance systems

Contribute to digitalization and integration of national surveillance systems through EU4Health grants for Member States.

Target: Improved digitalization and integration of national surveillance systems in EU/EEA Member States (2024–2027).

ECDC was established under Regulation (EC) No 851/2004 [85] which sets out the mission, structure, bodies and working arrangements. In 2022, the ECDC's mandate was extended [86] to allow it to provide the required scientific expertise, and to support measures in preparedness for and fight against serious cross-border threats to health in the EU.

The strengthened ECDC mandate [86] establishes the creation of The EU Health Task Force (EUHTF) which is an initiative to support countries in Europe and around the world by providing operational outbreak response and crisis preparedness related to communicable diseases or diseases of unknown origin. [87] [88] Through EpiPulse, EUHTF responds to specific requests coming from countries, from the European Commission or from other international partners, including requests for emergency response, investigation of outbreaks, operational research, rapid identification of gaps in preparedness, expert advice, guidance, or simulation exercises. Activities outside of the EU/EEA are operationalized in collaboration with the European Commission, and in particular with the Directorate-General for European Civil Protection and Humanitarian Aid Operations, and the GOARN.

The strengthened ECDC mandate will also have an impact on the reporting of notifiable diseases. Currently, in most but not all EU countries the reporting of notifiable diseases to the EU surveillance system is established by law. Moreover, the list of nationally notifiable diseases differs across member states. Therefore, so far, different data on a variety of infectious diseases are collected in member states. The ECDC (which coordinated competent authorities responsible for epidemiologic surveillance at EU/EEA level) has a structure in place with certain variables to be collected, which can be adjusted ad-hoc (e.g. for Mpox). [31] Event-based surveillance (non-structured information) is reported through EpiPulse events and indicator-based surveillance is reported through Tessy, currently transitioning to EpiPulse cases (see section 4.3). Case definitions (and other EU level standards such as list of reporting requirements, format, timeliness of reporting) are defined a priori, agreed with member states, and then used to guide the surveillance process.

The Early Warning and Response System[aa] (**EWRS**) [89], in congruence with EWARS at WHO (see section 4.2.6), supports coordinated risk management of serious all-hazard cross border threats to health, and documentation regarding the preparedness for such events (see Box 8). Furthermore, EWRS is used for selective exchange between member states e.g. on cross-border contact tracing. In case of a serious cross-border threat to health the Belgian SPF is asked to report to EWRS which both ECDC and WHO have access to. ECDC puts the EWRS signal into EpiPulse.

Box 8 – Early Warning and Response System (EWRS) practical outline

EWRS has been successfully used to alert, share information and coordinate measures in response to cross-border events of communicable diseases, with current and previous outbreaks managed, such as COVID-19, Mpox, pandemic influenza A(H1N1), Ebola, etc. The first notification of what later became known as SARS-CoV-2 (the virus causing COVID-19) was posted by the Commission as early as 9 January 2020, days after China signaled the existence of an unknown virus. During the COVID-19 response, the EWRS also supported the exchange of passenger locator forms data for cross-border contact tracing. Contact tracing is an essential tool for an effective response that allows possibly infected individuals to be rapidly identified to isolate, test, or treat them. This, in turn, helps to stop or slow down the spread of the disease. Exchanging passenger data through EWRS was made possible thanks to two legal acts [90] [91]

To enhance these processes, the new EU Regulation on serious cross-border threats to health [92], implies that a new list of notifiable diseases will be established in 2025 and will be directly applicable at national level (after an adaptation period of probably one year). The member states remain responsible for deciding which surveillance system to use to report data (e.g. sentinel network of laboratories versus mandatory notification of infectious diseases). Concerning the technical framework for reporting, ECDC already has 'reporting protocols' for all diseases under surveillance and a meta-dataset. These documents define all the variables to be reported, their format, the format of the files, the validation rules, etc., and will be updated once the new list of notifiable diseases is approved. Furthermore, as part of the implementation of Article 14 of the Regulation, ECDC will be defining surveillance standards, i.e. for each disease under surveillance ECDC will specify the intended surveillance objectives, the data needed to fulfil those objectives, the frequency of reporting, minimum data quality requirements [93], etc. Box 9 lists two organizations focusing on enhancing data quality. It should be taken into account that complying with data quality characteristics is challenging at this moment even in the context of data collection in registries and standardized databases. Complying with data quality characteristics in the event of an outbreak of an unknown pathogen will be even more challenging, and perhaps not realistic.

[aa] A rapid confidential web-based alert system for notifying alerts at EU level on serious cross-border CBRNe threats to health. The European Commission owns the system, and the ECDC operates the IT platform.

Box 9 – Examples of organizations aiming to enhance data quality

The **European Institute for Innovation through Health Data (i~HD)** is a European, not-for-profit organization which aims to facilitate the optimal uses of health data through a series of complementary activities. They state that data quality relates to 9 key principles: completeness, consistency, correctness, uniqueness, stability, timeliness, contextualization, trustworthiness and representativeness.

The **European Health Data Space (EHDS)** is an EU initiative aimed at creating a secure framework for health data sharing (for primary and secondary use) across Europe. It enables individuals, researchers, and healthcare providers to access and share health data for improving medical research, public health, and healthcare services. The EHDS is part of the EU's broader digital strategy to enhance data interoperability and digital transformation in healthcare across member states.

5 DISCUSSION AND POLICY RECOMMENDATIONS

Belgium has a mandatory reporting system for certain infectious diseases, but it has been shown not to be sufficiently resilient in the context of a public health emergency. Moreover, to obtain a case definition in (re)new(ed) pathogens with pandemic potential, rapid collection and transfer of data on the first 100 cases across regions is necessary, and has to be harmonized by a national surveillance organization (e.g. Sciensano in Belgium) to make it possible to assess data and inform policymakers.

Experts in the field question the compliance of clinicians in reporting the many infectious diseases listed as obligatory to report, also given the variations in reporting methods that exist between regions but also within each region. One of the main reasons mentioned for non-reporting is the lack of feedback after such reporting efforts. Therefore, clear communication to the clinicians will be key when a new infectious disease outbreak is declared to be of public health importance and the obligatory reporting is triggered. In addition, experts feel that a rapid feedback loop of the pooled analyses and responses observed to initiated treatments will likely stimulate the complete and rapid reporting of cases by those clinicians. Of note, a feedback loop is integrated in the Norwegian MSIS system. Another possible approach to enhance reporting of clinical cases without lab diagnosis could be to install automatic alerts in the hospital information systems.

It is clear that these challenges should be tackled as soon as possible as threats will continue to emerge. As governments tend to relay their support and regulations on scientific evidence and advice by experts, the process should be unraveled and solutions should be sought to overcome these challenges. Although these concerns were expressed by several papers and at many national and EU conferences, adequately addressing these challenges requires a coordinated effort involving governments, public health agencies, healthcare providers, researchers, and international organizations.

In line with the ECDC Public Health Emergency Preparedness Assessment of Belgium in May 2024 [32], there is ongoing inter-federal coordination work to improve preparedness in data collection for potential public health emergencies such as zoonotic Influenza or Mpox. Through the use of the Mandatory Notification of Infectious Diseases, public health institutes should be able to gather essential data on key epidemiological parameters such as incubation period, duration of contagiousness, transmission route, case definition, symptoms, patient risk factors and whether pre-symptomatic transmission occurs. In particular, it will be challenging to make these mandatory reporting systems flexible enough. This way an evidence-based assessment can be provided through interoperable nationally collected data which can be used as evidence for RAG's risk assessments. This information should consequently advise the RMG on appropriate measures to take based on available and emerging evidence. However, this goal requires:

1. A priority list of pathogens for which datasets have to be prepared and harmonized at the subnational level,
2. Inter-federal coproduction of epidemiological research protocols with interoperable databases across the subnational Health Authorities, and
3. A clear governance structure to determine when the protocol is initiated and when it stops (e.g. after description of the first 100 cases).

Ideally these initiatives – If feasible – should be aligned at an international level (e.g. ECDC) to rapidly gain sufficient data on the first cases through a larger European sample size. Since November 2022, as a response to the COVID-19 pandemic, the European Regulation describing the role and mandate of ECDC has been expanded (see section 5). Coordination of these types of European-level activities could be integrated within the expanded ECDC mandate, e.g. through the European Union Health Task Force (EUHTF).

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Colophon

The Rapid Response Reports aim to answer urgent questions from decision-makers. They apply expedited methods to produce timely evidence-based recommendations.

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