Country report: ECDC Public Health Emergency Preparedness Assessment for Spain, 2024

Under Article 8 of the Regulation (EU) 2022/2371

ECDC ASSESSMENT

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Abbreviations

AMR	Antimicrobial resistance
CCAES	Coordinating Center for Health Alerts and Emergencies
CNE	National Centre for Epidemiology
CNM	National Centre for Microbiology
CISNS	Interregional Council (Consejo Interterritorial del Sistema Nacional de Salud)
CSIC	Spanish National Research Council
EEA	European Economic Area
EQAs	External quality assessments
EU	European Union
EWRS	Early Warning and Response System
HAI	Healthcare-associated infection
IHR	International Health Regulations
INGESA	National Health Management Institute
IPC	Infection prevention and control
ISCIII	Instituto de Salud Carlos III
ISARPAE	Improving surveillance of antibiotic-resistant *Pseudomonas aeruginosa* in Europe
LTCFs	Long-term care facilities
MAPA	Ministry of Agriculture, Fisheries and Food
MICIU	Ministry of Science Innovation and Universities
MITECO	Ministry of Ecological Transition and the Demographic Challenge
PHEPA	Public Health Emergency Preparedness Assessment
PPS	Point prevalence survey
RASVE	Health Veterinary Alerts System
RCCE-IM	Risk Communication, Community Engagement and Infodemic Management
SIVIES	Spanish Surveillance System platform
SPAR	State Party Self-Assessment Annual Report
RedLabRA	Spanish Network of Laboratories for Surveillance of Resistant Microorganisms
WGS	Whole genome sequencing

Executive summary

Introduction

The aim of the Public Health Emergency Preparedness Assessment, as mandated in Article 8 of the Regulation (EU) 2022/2371 on serious cross border threats to health, is to improve prevention, preparedness and response planning in European Union/European Economic Area (EU/EEA) countries through the implementation of recommendations following individual country assessments. As specified in the Regulation, each EU/EEA country will undergo an assessment every three years, with the first cycle of these occurring between 2024 and 2026.

This report presents the findings of the first assessment conducted in Spain. This involved a desk review of relevant documents, followed by a five-day country visit that took place between 14 and 18 October 2024. As per the assessment methodology, all of the 16 capacities included in Article 7 of the Implementing Regulation (EU) 2023/1808 self-assessment template were assessed, with five of them considered in-depth: Laboratory (Capacity 3); Surveillance (Capacity 4); Health Emergency Management (Capacity 6); and Antimicrobial resistance (AMR) and healthcare-associated infections (Capacity 12) and Risk communication and community engagement (Capacity 8). The report also provides specific recommendations for the country to improve prevention, preparedness and response planning. Spain is requested to provide an action plan addressing these recommendations within nine months of the receipt of this report.

Key findings

Spain has strong collaboration between sectors. However, its decentralised health system requires strengthened coordination between national and regional levels, supported by clear legal frameworks, to ensure effective preparedness and response to public health emergencies. The country is in the process of developing key pieces of legislation, including a Royal Decree for the development of the National Preparedness and Response Plan, and intends to establish a National Public Health Agency.

The Coordinating Center for Health Alerts and Emergencies (CCAES) at Spain's Ministry of Health serves as the focal point for both the Early Warning and Response System (EWRS) and the International Health Regulations (IHR). The Centre also has its own system of daily epidemic intelligence to monitor for potential threats.

If a public health event occurs, the CCAES works closely with the National Centre for Epidemiology (CNE), National Centre for Microbiology (CNM), regional public health authorities and other sectors to monitor key epidemiological indicators and produce risk assessments when needed.

After the COVID-19 pandemic, the Influenza Surveillance system in Spain was gradually replaced by an integrated surveillance system for influenza, COVID-19 and respiratory syncytial virus (RSV). A robust, tier-based laboratory system is in place in Spain, serving clinical diagnostics and public health, including decentralised capacities for advanced genomic characterisation. The Spanish Surveillance System platform (SIVIES) at CNE guarantees confidentiality in event notifications, and there is a 24/7 on-duty system in place.

One of the major gaps identified during the mission was the lack of dedicated staff for Risk communication, Community engagement and Infodemic Management (RCCE-IM) activities at the Ministry of Health. Communication efforts are highly subject to the political situation, and there is a need for technical RCCE-IM capacities that operate independently of political changes.

Main recommendations for each capacity assessed in depth

Health emergency management (Capacity 6)

- Finalise the National Preparedness and Response Plan that is currently under development; during this process, introduce a formal prioritisation process for all health threats, a formal incident management system and a section on recovery that outlines and assigns responsibilities.
- Better define the risk assessment procedure, including protocols for specific threats, triggering criteria, stakeholders to be consulted, approach to uncertainty and the activation of response based on risk assessment.
- Improve the collaboration between public health and healthcare sectors; provision of a specific intersectoral 'Asistencial' Committee is included in the forthcoming National Preparedness and Response plan. Formalise the intersectoral collaboration for preparedness and response with all involved sectors.
- Map the feasible public health and social measures, taking into consideration the complex structure of public health in Spain, and develop procedures for designing, implementing and evaluating such measures.
- Ensure that operational plans align with the National Preparedness and Response Plan, when it has been adopted, and test them through a multilevel simulation exercise.

- Sustain medical countermeasures (MCMs) preparedness over time by addressing access to the crisis-relevant MCMs deemed most suitable for specific products or categories, including their raw materials or components. This concept should be outlined in the national preparedness plan and the methodology for identifying crisis-relevant MCMs should be formalised. Sustainability of the national stockpile should also be ensured and its eventual format defined.

Laboratory (Capacity 3)

- Document the public health laboratory system and formalise the plan for laboratory response in emergency situations. This plan should be linked to the general National Preparedness and Response Plan and include aspects for scaling-up capacity within the National Centre for Microbiology, as well as other laboratories in Spain.
- Formalise the current agreements for services requiring BSL4 laboratories.
- Finalise and implement guidelines/regulations on biosecurity.

Surveillance (Capacity 4)

- Continue to improve the surveillance system for acute respiratory infections, including improving the integration of data, further automating the system, implementing the results from the planned evaluation, and improving data comparability among regions to increase timeliness and address knowledge gaps (e.g. transmissibility, severity, vaccine effectiveness) for seasonal, emerging and re-emerging pathogens.
- Establish a systematic process for sharing data on hospital indicators, testing capacity and contact tracing capacity at the national level and among regions during a crisis, without requiring a national State of Alert.
- Ensure sustainability of the wastewater surveillance data and its further integration and harmonisation with other surveillance systems.
- Foster sustainable availability of mathematical modelling capacity to reinforce near-term forecasting during emergencies.

Antimicrobial resistance and healthcare-associated infections (Capacity 12)

- Strengthen national engagement with entities that directly engage with healthcare providers and healthcare facilities. This can be achieved via close collaborations with AMR and HAI counterparts at the autonomous community public health agencies, professional or scientific societies, and other government agencies that have oversight of healthcare professionals and healthcare services.
- Establish a basic and scalable surveillance system with minimum mandatory reporting from all autonomous regions to better understand incidence of priority multidrug-resistant organisms.
- Strengthen activities that produce data-driven infection prevention and control (IPC) training and feedback interventions in hospitals and long-term care facilities. National prevention and control priorities should be based on gaps in IPC identified using surveillance and outbreak data.

Risk communication and community engagement (Capacity 8)

- Develop a formalised, structured approach to Risk communication, Community engagement and Infodemic Management (RCCE-IM) both at central and decentralised levels, with strategies and standard operating procedures. This should include clear mechanisms to scale-up RCCE-IM during emergencies and intersectoral coordination mechanisms for RCCE-IM emergency preparedness and response.
- Include the RCCE-IM pillar in the National Preparedness and Response Plan.
- Allocate and train dedicated staff for RCCE-IM functions within the Ministry of Health, the CCAES, and/ or at regional levels. Include Behavioural and Cultural Insights (BCI) as a structural pillar of the RCCE-IM process.

Conclusions

The PHEPA mission in Spain was conducted successfully and included the participation of a wide range of national stakeholders from diverse sectors, which resulted in very rich discussions. The country has a decentralised health system, with all public health capacities (with the exception of Foreign Health) transferred to its Autonomous Regions, which closely collaborate with the national level through the Ministry of Health in charge of supra-regional coordination. A strong cross-sectoral collaboration was observed; however, communication and collaboration processes are not formalised or documented. Risk communication and community engagement is one of the capacities identified as having great potential to improve. In addition, the National Preparedness and Response Plan should be finalised and approved, ensuring the implementation of all its components. This report provides specific recommendations for the country to improve prevention, preparedness and response planning. Spain is requested to provide an action plan addressing these recommendations within nine months of the receipt of this report.

Introduction

The aim of the Public Health Emergency Preparedness Assessments, as mandated in Article 8 of the Regulation (EU) 2022/2371 on serious cross-border threats to health, is to improve prevention, preparedness and response planning in EU/EEA countries through the implementation of recommendations following individual country assessments. As specified in the Regulation, each EU/EEA country will undergo an assessment every three years, with the first cycle of these occurring between 2024 and 2026.

This report presents the findings and recommendations of the first assessment conducted in Spain. This process involved a desk review of relevant documents, followed by a five-day country visit.

Background and legal basis

During the COVID-19 pandemic it was recognised that the legal framework for combatting serious cross-border threats to health, provided for in Decision No 1082/2013/EU, needed to be broadened and enhanced to ensure a more effective response across the European Union (EU) to deal with health-related emergencies. Hence, the European Commission developed and published on 23 November 2022 the Regulation (EU) 2022/2371 on serious cross-border threats to health [1].

Within this Regulation it is recognised that prevention, preparedness and response planning are essential elements for combatting serious cross-border threats to health. In addition to creating a Union prevention, preparedness and response plan (Article 5 of the Regulation), the Regulation also outlined the importance of updating and seeking coherence with Member States' prevention, preparedness and response plans (Article 6 of the Regulation).

To monitor the implementation of the plans, the Member States shall report to the European Commission regarding their prevention, preparedness and response planning at the national level every three years. For this purpose, a self-assessment template was developed under Article 7 of the Regulation [2], complementary to the International Health Regulation (IHR) State Party Self-Assessment Annual Report (SPAR) [3].

In order to support the assessment of these plans, Article 8 of the Regulation indicates that ECDC has the responsibility – in coordination with relevant Union agencies and bodies – to conduct assessments of all 30 European Union and European Economic Area (EU/EEA) countries every three years. The procedures, standards and criteria for the assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan are defined by the Commission Delegated Regulation (EU) 2024/1232, adopted in March 2024 [4].

ECDC has developed a methodology for Public Health Emergency Preparedness Assessment to implement Article 8 of the Regulation (EU) 2022/2371. The assessment process addresses the 16 capacities included in the Article 7 self-assessment template and is designed to maintain consistency within the EU/EEA countries throughout the three-year cycle, while allowing for adaptation of plans if the national circumstances require.

Aim and objectives

The aim of the ECDC Public Health Emergency Preparedness Assessment process, drawn from Article 8 of the Regulation on serious cross-border threats to health, is to improve prevention, preparedness and response planning in EU/EEA countries through the implementation of recommendations following individual country assessments. Countries are asked to provide an action plan addressing the proposed recommendations of the assessment within nine months of the receipt of the ECDC report.

[1] European Commission (EC). Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. Brussels: EC; 2022. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2371&from=EN

[2] European Commission (EC). Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council. Brussels: EC; 2023. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1808

[3] World Health Organization (WHO). IHR (2005) States Parties self-assessment annual reporting tool, 2nd ed. Geneva: WHO; 2021. Available at: https://www.who.int/publications/i/item/9789240040120

[4] European Commission (EC). Supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan. Brussels: EC; 2024. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401232

The specific objectives of the assessment process are to:

- Assess the countries' self-assessments of preparedness in the 16 capacities covered by the outputs from the most recent International Health Regulation State Party Self-Assessment Annual Report and the Article 7 template.
- Collaborate with countries to identify good practice, challenges, bottlenecks, gaps or areas for improvement concerning the 16 capacities referred to in Article 7 (a list of the capacities assessed is available in Annex 1).
- Encourage the inclusion of key elements within the prevention, preparedness and response planning structure such as cross-sectorial and cross-border coordination, crisis management, response governance, communication, plan testing, evaluation and regular reviews, according to the lessons identified from the response to public health emergencies.
- Use the opportunity of a standardised approach to the assessment process to contribute to the improvement of EU/EEA prevention, preparedness and response capacities by promoting a common understanding of key elements and a coordinated approach.
- Provide support to countries in enhancing their national prevention, preparedness, and response capacities through recommendations based on the assessment, and provide targeted assistance upon request.

Assessment process

An ECDC-led team composed of 10 ECDC experts; four experts from the European Commission's Directorate-General for Health & Food Safety, the Health Emergency Preparedness and Response Authority and the World Health Organization Regional Office for Europe; and one national expert from Portugal was assembled to conduct the assessment, in collaboration with the focal point and national experts from Spain. The assessment process consisted of a desk review phase and a country visit that took place between 14 and 18 October 2024.

As per the established process, the team reviewed Spain's responses to the Article 7 self-assessment questions, with five of them considered in depth: Laboratory (Capacity 3); Surveillance (Capacity 4); Health Emergency Management (Capacity 6); Antimicrobial resistance (AMR) and healthcare-associated infections (HAIs) (Capacity 12) and Risk communication and community engagement (Capacity 8).

The host country experts participated in the mission with an open and transparent approach, including sharing relevant documents for the assessment, engaging in a productive discussion, and involving a wide range of stakeholders who enriched the dialogue, contributed multiple perspectives and delivered presentations on each in-depth capacity. The country focal points were present throughout the discussions to ensure a clear understanding of the country's organisational structure. Further details regarding the practical aspects of the mission are available in Annex 2.

Main findings and overarching recommendations

Spain operates as a decentralised country, with all public health capacities (except Foreign Health) transferred to its Autonomous Regions, which closely collaborate with the national level through the Ministry of Health in charge of supra-regional coordination in health policy, health planning and guidelines; coordination of surveillance and health information systems; foreign and border health related issues and legislation on pharmaceutical and chemical products. Several legislative measures are currently under development, including a Royal Decree focused on the development of a National Preparedness and Response Plan for Public Health Threats and a legal framework to establish a National Public Health Agency, which is anticipated to consolidate public health resources and play a key role in preparedness and response efforts.

Spain relies on its own system of daily epidemic intelligence to monitor potential threats. The Coordinating Center for Health Alerts and Emergencies (CCAES) at the Ministry of Health serves as the focal point for both the Early Warning and Response System (EWRS) and the International Health Regulations (IHR). Although the current epidemic intelligence system allows for careful monitoring of threats, the process is not automated – though several improvements in this area have been conducted recently. All signals are discussed in a daily roundtable meeting. A daily alert report is generated, and the experts participating in the daily threats monitoring meetings at the CCAES discuss and decide which relevant signals or alerts should be included and distributed. The alert report is shared with the regions and relevant networks. The Foreign Health department at the Ministry of Health (Sanidad Exterior) monitors global health situations that may impact Spain, especially concerning travellers. The unit is responsible for organising and guaranteeing the provision of healthcare for international travel, the prevention of traveller diseases and injuries, and international vaccination services. It is also responsible for issuing specific alerts and recommendations to international vaccination clinics across the country and participates in the daily threats monitoring meetings organised by the CCAES, contributing to risk assessments when necessary.

If a public health event occurs, the CCAES works closely with the National Centre for Epidemiology (CNE), National Centre for Microbiology (CNM), and regional public health authorities to monitor key epidemiological indicators. The CCAES is responsible for coordinating the development of risk assessments when needed, following the ECDC methodology and involving key relevant stakeholders. The final risk assessment is published on the Ministry of Health website. If the risk affects a specific region, the assessment is conducted in collaboration with regional authorities. Stakeholders, including regional authorities, trust this process and frequently consult with the CCAES.

The Spanish Surveillance System platform (SIVIES), hosted at CNE, guarantees confidentiality in event notifications, and there is a 24/7 on-duty system in place. Spain is developing new tools for routine surveillance and notifications across regions. Spain's Autonomous Regions generally perform well in regional surveillance. Regular updates are received from neighbouring countries like Portugal.

A robust tier-based laboratory system is in place in Spain, serving clinical diagnostics and public health, including decentralised capacities for advanced genomic characterisation. The CNM also has a rapid response system (24/7) to carry out rapid diagnostics in case of a microbiological alert. There is also scientific-technical infrastructure in place, the Biological Alert Laboratory Network (RE-LAB), composed of specialised microbiology laboratories that support the National Security System in responding to risks in emergency situations caused by the accidental or intentional release of biological agents.

One of the major gaps identified during the mission is the lack of dedicated staff for RCCE-IM activities at the Ministry of Health. Communication efforts are highly subject to the political situation, and there is a need for technical RCCE-IM capacities that operate independently of political changes.

Recommendations

- Ensure the finalisation and adoption of legal texts pertaining to public health functions (e.g. the National Preparedness and Response Plan, the founding of the National Public Health Agency).
- Ensure consistency in collaboration between regional and national levels to strengthen preparedness and response in emergencies.
- Formalise the collaboration and communication mechanisms between different sectors and stakeholders to support emergency preparedness and response.
- Develop a strategy to ensure sufficient resources in public health to prevent, detect and respond to public health emergencies in the country, including financial and human resources.
- Conduct national activities to strengthen risk communication, community engagement and infodemic management (RCCE-IM) capacities, with clearly designated human resources at all levels, independent of political hierarchy. Include the RCCE-IM pillar in the National Preparedness and Response Plan.
- Implement processes allowing for mobilisation and timely activation of functions necessary during public health events that do not require a national State of Alert to be declared.

Findings and recommendations per capacity

A list of the capacities that were included in the assessment is available in Annex 1.

Capacities assessed in depth

Health emergency management (Capacity 6)

Management of health emergency response

Public health services in Spain are decentralised to the 19 Autonomous Regions, as are healthcare services. The Autonomous Regions are responsible for capacity-building, including public health training. However, several coordination bodies are in place to ensure that sufficient consultation happens between the Ministry of Health (mainly the CCAES) and the regional-level public health authorities. A technical working group (Health Alerts and Preparedness Board) first reviews proposed changes, protocols and plans, as well as other public health documents, which are then approved by the Public Health Commission and finally adopted by the Interregional Public Health Council.

Several response plans and protocols were shared with the assessment team in advance of the mission. These addressed specific communicable disease threats (e.g. vector-borne diseases, mpox, rabies, anthrax spore incidents, etc.), providing a good overview of the response structure and capacities in Spain.

The Ministry of Health in Spain is undertaking a significant reform in the area of public health, aiming to establish a National Public Health Agency, which will consolidate public health surveillance, diagnostic capacity and preparedness at the national level. The CCAES is currently putting a lot of effort to develop a National Preparedness and Response plan to address all hazards. This has undergone the first stages of technical consultation with the Autonomous Regions and is currently in consultation with other sectors. It will eventually be adopted in the legal framework as a Royal Decree, expected in 2025 or 2026. This plan aims to incorporate several of the lessons from the response to the COVID-19 pandemic. Therefore, it introduces the possibility to declare a 'Public Health Emergency of National Concern' for Spain, so as to avoid the immediate declaration of a national 'State of Alarm'. In addition, there is the introduction of several new coordination committees during a public health emergency, like the Coordination Committee (CECO), the 'Asistencial' Committee (to support collaboration between the public health and healthcare sectors) and a Risk Communication Committee.

For the time being, the CCAES at the Ministry of Health is the main actor in the area of epidemic intelligence, risk assessment of public health threats, emergency preparedness and response, and coordination of public health

response with few human resources. The CCAES' closest collaborators include ISCIII (CNE, CNM) and the Autonomous Regions, as well as the network of CBRN laboratories (Biological Alert Laboratory Network (RE-LAB)), the food safety agency (Spanish Agency for Food Safety and Nutrition – AESAN) and agriculture stakeholders, as they are frequently involved in responding to food-borne outbreaks. Civil Protection includes the participation of public health services only on demand, although post-pandemic they have created a Scenario 'E' in the national plan (PLEGEM) to accommodate large health crises, where the health sector is in the lead. Collaboration with other sectors (e.g. research, education, transport, tourism, etc.) is mainly ad hoc (e.g. for the introduction of public health and social measures during the pandemic).

Finally, cross-border collaboration with Portugal and France is happening as needed for outbreaks at bordering regions, and some initiatives also exist at the regional level.

Emergency logistic and supply chain management

Spain has made significant progress in Medical Countermeasures (MCM) preparedness for health emergencies through the decision to increase the scope and size of the strategic national stockpile. Building on this development, the different draft legislations can be viewed as an opportunity to implement holistic MCM preparedness sustainably by designating effective and complementary interventions for MCM access.

Access to crisis-relevant MCMs is provided at the national level by the National Health Management Institute (INGESA) and in the regions through counterparts. Spain has in place a list of crisis-relevant MCMs which informs decisions towards the make-up of the national stockpile. This list is drawn up by an established working group chaired by INGESA. Additionally, through the Spanish Agency of Medicines and Medical Devices (AEMPS), Spain defines a list of critical medicines irrespective of health emergencies, whose supply and demand is continuously monitored and for which there are measures to restrict export based on a demand-supply forecast. Draft legislation to implement measures to increase strategic autonomy have scoped three value chains to be addressed, of which one is critical medicines (but not necessarily crisis relevant, as defined in a specific health emergency).

Demand estimates of crisis-relevant MCMs to inform stockpiling are based on data from COVID-19, as aggregated by INGESA and for CBRN threats based on discussions in an ad hoc working group with the Ministry of Defence. The national stockpile is in the process of being set up with an appropriate contractor already in charge of logistics of the future stock. The process to define the concrete nature of the stockpile is ongoing.

Recommendations

- Finalise, approve and ensure the implementation of all components of the National Preparedness and Response Plan for Health Threats. In the current phase, introduce the following to complement already ongoing work:
  - a more formal prioritisation process for health threats to address all hazards;
  - an official incident management system in the response, as the incident management functions currently exist but are mostly self-regulated and informal.
- Better define and formalise the procedure for rapid risk assessment, e.g. triggering criteria; who/how external consultants are involved per type of threat; how it reaches policy makers; and criteria for re-assessment. Define emergency response activation procedures for response actions based on risk assessment.
- Develop a list of feasible public health and social measures, based on the experience and evaluation work performed for the COVID-19 pandemic, in a cross-sectoral process with the Autonomous Regions, especially addressing the circulation of respiratory pathogens. As per guidance from the World Health Organization (WHO) and ECDC, also develop procedures for the implementation and evaluation of public health and social measures considering positive and negative health impacts.
- Support and strengthen the CCAES to fulfil its public health role as the main actor in the area, until the reform is completed and the National Public Health Agency is established.
- Improve the collaboration between public health and healthcare sectors at national and regional levels.
- Formalise intersectoral collaboration for preparedness and response for all threats, with other sectors beyond food safety and agriculture.
- Sustain MCM preparedness over time by addressing access to the crisis-relevant MCMs deemed most suitable for specific products or categories, including their raw materials or components. This concept should be outlined in the national preparedness plan.
- Ensure coherence on MCM preparedness and response governance and envisioned interventions in the relevant draft legislations.
- Formalise the methodology for identifying crisis-relevant MCMs and distinguish from strategic medicines; ensure conformity of terms with those in the Emergency Framework Regulation.
- Formalise governance of working groups responsible for MCM-related decision-making, in preparedness and during crisis, including strong links between public health and INGESA.
- Explore data-sharing on supply and demand from the regional to the national level and develop harmonised reporting methodologies, if necessary.
- Explore adapting mechanisms to improve national supply of strategic medicines to crisis-relevant MCMs.
- Ensure the sustainability of the national stockpile and define its eventual format.

- Update threat-specific response protocols and plans for MCM recommendations and add how access to these MCMs can be facilitated.

Laboratory (Capacity 3)

Spain has a robust, tier-based laboratory system in place that serves national clinical diagnostics and public health. The core of the laboratory system is the capacities offered by the CNM, which has a mission to support the national public health system and strengthen capacities for diagnostics and surveillance.

CNM conducts activities in diagnostics, reference services and research with 13 operational national reference laboratories that each cover a single disease or a group of diseases. CNM offers facilities for BSL3 diagnostics and characterisation and a BSL4 laboratory is currently under construction, expected to be completed in 2028. In the meantime, activities that requires BSL4 facilities are accessed through collaborations with institutions in other EU countries.

Coordination with local and regional laboratories is mainly maintained through the establishment of technical or operational working groups. Within these groups, activities to promote data comparability and build capacity are exercised, such as external quality assessments (EQAs) and implementation of national quality standards.

Spain has a plan, and the organisational capacities, to scale-up laboratory testing capacity in the event of a public health emergency, as shown during the national response to COVID-19 and during the mpox outbreak in 2022. As part of this plan, a rapid response team can be mobilised and specific laboratory tests can be prioritised in CNM laboratories, independent of their main pathogen specialty. Funding for enhanced laboratory activities in response to emergencies comes from various stakeholders, including the Autonomous Regions, Instituto de Salud Carlos III (ISCIII), and government ministries. The CNM estimates that the maximum weekly testing capacity in Spain can cover approximately 0.1–1% of the population. The plan for scaling-up laboratory capacities is described in an unofficial document, and no link with the general preparedness plan was confirmed during the meeting. Moreover, mobilisation of non-CNM laboratories, such as those in other sectors, are not detailed in the plan.

The Spanish laboratory system is flexible and capable to adapt to new threats/targets, including operationalisation of new assays in reference and regional laboratories, and modifying systems for reporting data to the national level. This flexibility was illustrated through the example of the 2024 national response to Oropouche virus, in which analytical methods where integrated into the laboratory data reporting system within two weeks. As with other countries, the CNM indicated that the time-limiting factor for the adjustment of services offered by a public health laboratory network is often the availability and distribution of positive controls to that network.

The capacity for whole genome sequencing (WGS) is distributed to over 49 regional laboratories across Spain. The RELECOV network performs genomic sequencing of SARS-CoV-2, influenza and RSV for national and EU-level surveillance. Genomic data sequences data from RELECOV laboratories are transferred to CNM through SFTP servers. CMN compiles the national genomic information for these viruses for ECDC-coordinated surveillance activities and develops protocols and tools for WGS application in regional laboratories. Data from the RELECOV network can be integrated into the national surveillance system.

The Biological Alert Laboratory Network (RE-LAB) is scientific and technical infrastructure established by Order PRE/305/2009 of the Ministry of the Presidency. This network is composed of reference laboratories specialised in different areas, such as public health, animal health, environmental health, food safety, and plant health. The RE-LAB, whose scientific and technical management is under the Ministry of Science, Innovation, and Universities through Instituto de Salud Carlos III, aims to support the National Security System in responding to risks and threats related to the accidental or intentional release of biological agents.

Aspects of biosafety are well developed and applied in all laboratories in Spain, based on a set of regulations aimed at protecting public health, worker safety, and the environment from biological risks. Biosecurity, which refers to protecting biological agents from people with potentially harmful intentions, is less developed than biosafety in Spain. The expected output from ongoing work to improve biosecurity in Spain is a new regulation or 'Royal Decree'.

Although there is no mandatory laboratory quality system in Spain, approximately 70% of laboratories have voluntarily implemented a quality system or undergone accreditation following international standards.

Recommendations

- Formalise the plan for laboratory response in emergency situations and link it to the general National Preparedness and Response Plan. This should include a full description of the public health laboratory surveillance system, including data and information flow and expected use in specific emergencies, and the process to 'scale-up' laboratory capacity within the National Centre for Microbiology and other laboratories across Spain.
- Ensure that a formal agreement and funding mechanism are in place across sectors for rapid deployment of additional laboratory capacity.
- Formalise the current agreements for services requiring BSL4 laboratories.
- Include high-volume testing for crisis situations in simulation exercises and/or stress tests across sectors.
- Finalise and implement guidelines/regulation on biosecurity.
- Work towards having a higher proportion of laboratories performing clinical diagnostics, applying quality standards or being accredited/licenced.

Surveillance (Capacity 4)

In October 2020, after the COVID-19 pandemic had begun and following the recommendations from the World Health Organization (WHO) and ECDC, the previous Influenza Surveillance System (Sistema de Vigilancia de Gripe en España (SVGE)) evolved into an integrated surveillance system for influenza, COVID-19 and RSV. This new surveillance system for acute respiratory infections (Sistema de Vigilancia de Infección Respiratoria Aguda (SiVIRA)) includes acute respiratory infections (ARI) from primary care and severe acute respiratory infections (SARI) from hospitals. This system was implemented gradually, at national and regional levels, with CNE as the coordinating party.

The SiVIRA has clear protocols for ARI and SARI, which includes two components of the surveillance of respiratory infections: syndromic, with the automatic extraction of codes associated with ARI/SARI following WHO definitions as references, and systematic, with a representative sample of the total population per age, gender and rural/urban population. Sentinel cases are selected twice a week and tested for influenza, SARS-CoV-2 and RSV, using the total number of tested hospitalised patients for those days as the denominator. The positive samples of these sentinel cases are further sequenced: all cases for SARS-CoV-2, a representative sample for influenza and all cases for RSV, depending on the laboratory capacity of each region. In addition, the National Centre for Microbiology will sequence samples from regions without this laboratory capacity.

Each Spanish Autonomous Region decides on how to circulate the data collected in SiVIRA within the region. The National Centre for Epidemiology collects data from the regions and prepares a weekly report that is shared every Wednesday afternoon with all SiVIRA members in the regions, ISCIII, the CCAES and the Public Health Directorate of the Ministry of Health, and published every Thursday on the ISCIII website.

The SiVIRA is partially automated, especially for the non-sentinel data from primary care; however, it requires manual validation of admissions in most of the hospitals and some of the data cannot be extracted automatically (i.e. date of onset, clinical presentation, comorbidities and intensive care unit (ICU) admission). The selection of patients for being tested is automated in some regions in primary care and hospitals, but many of the sites still rely on individual judgement from general practitioners (GPs). This automation is being improved, as Spain participates in the ESURE-SARI and are undergoing an evaluation of the system focused on automation in hospitals.

The surveillance system for respiratory infections can scale-up during a pandemic due to the high number of reporting sites, which covers 15% of the population in primary care and 25% of the population in hospitals, with 18 of the 19 regions participating in this reporting (and the remaining region will join soon). Likewise, the syndromic component in primary care is exhaustive, based on a centralised databases in 15 of the 18 regions. The systematic component could be expanded to additional centres. Moreover, the system is already very timely, reporting each Wednesday data up to the previous Sunday, and an increase in this aspect would require other changes in the system (e.g. dissociating the daily syndromic component from the systematic testing that only runs two days a week). Furthermore, the RELECOV network has 49 laboratories with capacity for WGS characterisation. Some difficulties when scaling-up the system are different codes used in hospitals, different testing capabilities and strategies, and challenges in expanding the number of hospitals.

Data on hospital and testing indicators (i.e. hospital bed capacity, hospital ICU capacity, hospital emergency room capacity, hospital occupancy, hospital utilisation and testing capacity) are only available for public health in some regions. There was a good experience during the COVID-19 pandemic in sharing these data at the national level; however, it is only shared at the national level in response to ad hoc requests or during a national State of Alarm. The contact tracing activities depend on the region and capacities to monitor this indicator varies per region.

There is a wastewater monitoring system with monthly sampling in place for SARS-CoV-2, focusing on variants of concern or variants under monitoring, as listed by ECDC. Wastewater monitoring is also planned for influenza under the Sub-Directorate of Environmental Health and Occupational Health of the Ministry of Health and within the Strategic Health and Environmental Plan (Plan Estratégico de Salud y Medio Ambiente (PESMA)). RSV was not included, since the virus is expected to be detected in wastewater treatment plants after it has been circulated in the community; thus, wastewater surveillance cannot serve as an early warning. An information system to better store these data is being developed.

The SARS-CoV-2 wastewater surveillance started in March 2020 as an early warning system for forecasting hospital occupancy and needs. It has shown to be a good indicator for this, with a short early warning time (about a week) in some regions. The objective of this wastewater surveillance has evolved during the different phases of the COVID-19 pandemic and afterwards to accommodate varying needs.

Spain has infrastructure for timely and ongoing assessment of a pandemic threat, i.e. for assessing transmissibility, route of transmission and effective reproduction number, severity, immunological correlates of protection, vaccine effectiveness, and epidemic trajectories and impact through mathematical modelling. Some of these indicators can be obtained from SiVIRA (e.g. transmissibility and severity, as per the WHO pandemic influenza severity assessment (PISA) guidelines).

In addition, Spain is active in vaccine effectiveness studies at national and EU levels within the Vaccine Effectiveness Burden and Impact Studies (VEBIS) network. Despite having mathematical modelling capabilities, these are not

available in a sustainable way and have relied so far on ad-hoc collaborations with universities and research institutions or through external subcontracting.

Spain has developed and implemented national guidelines and standard operating procedures for surveillance at national and regional levels and provides immediate and weekly reporting of events and/or data. The CCAES has established protocols to perform epidemic intelligence, sharing the results of this activity on a daily basis during weekdays to different national and international stakeholders, including from different sectors within the country. Moreover, there are protocols established for notifiable diseases from the Spanish Epidemiological Surveillance Network (Red Nacional de Vigilancia Epidemiológica (RENAVE)), which are being updated according to the Regulation (EU) 2022/2371 on serious cross-border threats to health and waiting for the implementing act regarding case definitions and type of surveillance per disease. There are epidemiological bulletins published every week with the epidemiological information on notifiable diseases.

Spain has developed mechanisms for managing detected events that are implemented at national, regional and local levels. If needed, there is the possibility to develop ad hoc protocols for new diseases, which are drafted by the CCAES and agreed with the CNE, CNM and other relevant stakeholders, and then shared and agreed with all the regions. Expert working groups ('ponencias') are formed and act to better coordinate work between the Ministry of Health and the Autonomous Regions.

Recommendations

- Continue improving the surveillance system for acute respiratory infections, including better integration of data, further automation of the system and increasing data comparability among regions.
- Establish a systematic process for sharing data on hospital and testing capacity at national and regional levels during a crisis, without requiring a national State of Alert.
- Ensure sustainability of the wastewater surveillance system and its further integration and harmonisation with other surveillance.
- Foster sustainable availability of mathematical modelling to reinforce near-term forecasting during emergencies.
- Call or organise working groups ('ponencias') for addressing public health events/emergencies at an early stage to ensure there is consistency in the response to the event from the different regions.
- Ensure good communication and collaboration among the regions to detect small outbreaks even at local levels.

Antimicrobial resistance and healthcare-associated infections (Capacity 12)

At the national level, the estimated incidence of bloodstream infections is increasing for the three pathogens targeted for reduction in the EU Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (2023). According to data from laboratories voluntarily reporting to EARS-Net, increases have been seen since 2019 for methicillin-resistant *Staphylococcus aureus* (MRSA; +9.7% in 2022), *Escherichia coli* resistant to third-generation cephalosporins (+29.5%), and *Klebsiella pneumoniae* resistant to carbapenems (+42.6%).

Relevant sectors in Spain recognise the scope of the challenge. In 2023, the Spanish Network on Public Health Surveillance included AMR and HAI in a legislative framework for the first time. The National Action Plan (NAP) on antimicrobial resistance (AMR) for 2025–2027 was approved and formally adopted in December 2024 by various supporting committees and by the Ministry of Health and Ministry of Agriculture, Fisheries and Food, and is awaiting approval by the Interregional Council (CISNS). With 10 years of experience compiling and implementing NAPs for AMR and three prior NAPs, Spain's multisectoral coordination of the NAP is well-established and well-resourced. National antimicrobial consumption (AMC) surveillance and antimicrobial stewardship actions are particularly strong, and there are continued efforts to enhance feedback on AMC to providers. National-level funds for NAP activities are available and accessible, but it was unclear to the national teams at the assessment whether there is NAP-dedicated funding at the level of the Autonomous Regions, which are responsible for major aspects of healthcare provision and assurance. ECDC recommendations for the NAP have now been achieved. The NAP now includes clear objectives with process and outcome targets, and NAP-related outputs are available publicly on a website that includes an online platform for stakeholder collaboration. Multi-sector and multiagency NAP activities are monitored annually, with annual reports published on the NAP website. Of note, the COVID-19 pandemic identified gaps in infection prevention and control (IPC) for long-term care facilities (LTCFs). The 2025–2027 NAP includes a focus on the LTCF setting for coordinated action, as well as establishment of surveillance of antifungal resistance and antifungal consumption. These additions are welcome, considering the burden of communicable diseases among the LTCF residents and the known risks for *Candida auris* outbreaks in healthcare in Spain.

Spain has significant experience of extensive surveillance for AMR and healthcare-associated infections (HAIs). This includes the annual point prevalence surveys (PPSs) of HAIs annually since 1990 (EPINE studies), with over 200 hospitals participating, and surveillance of phenotypic antimicrobial susceptibility testing results since the early 2000s within EARSS, the predecessor of the European Antimicrobial Resistance Surveillance Network (ECDC EARS-Net). Spain reports to EARS-Net annually, with approximately 30% coverage of the national population.

Since 2016, several surveillance protocols have been developed with agreement from surveillance network members. This includes routine surveillance of surgical infections, multidrug-resistant organisms (MRSA*, C. difficile*,

and carbapenemase-producing Enterobacterales), and outbreaks. Unfortunately, due to various issues (lack of digital development, human resources, and others) the implementation of these surveillance systems is still not complete. In 2021, the Spanish Network of Laboratories for Surveillance of Resistant Microorganisms (RedLabRA) was established to support ARHAI surveillance, including both public and private clinical microbiology laboratories with excellent geographical and population coverage. Institutions in Spain continue to have a leadership role internationally for HAI and AMR prevention and control, such as the RedLabRA-affiliated network 'ISARPAE' (improving surveillance of antibiotic-resistant *Pseudomonas aeruginosa* in Europe).

Spain continues to participate in ongoing ECDC-coordinated surveillance activities, including incidence surveillance in ICUs, ECDC PPSs of HAIs, antimicrobial use and structure and process indicators of IPC, in both hospitals and LTCFs. Spain is working towards automated collection of surveillance data for bloodstream infections among the Autonomous Regions with different digital systems. To date, there has been very active participation in two regions (Valencia, Murcia), voluntary participation from 11 regions, and an observer status in other regions.

A national commitment to HAI prevention is evident from the national patient safety strategy, the national hand hygiene surveillance program, and 'Zero' projects that include multimodal interventions for IPC and antimicrobial stewardship for hospitals and primary care. As Autonomous Regions have oversight of healthcare facilities and no attendees from the regional level were present for this assessment, we were unable to assess the implementation of IPC assessments and interventions at the regional and facility levels. The national teams from the attending organisations noted that regular coordination between HAI/IPC experts at the national and regional levels is challenging, and communication with healthcare facilities is therefore limited. There are no national procedures or protocols in place for screening patients for multidrug-resistant organism (MDRO) carriage at hospital admission; however, national experts believe that guidance from professional/scientific societies is being followed.

Oversight of IPC in healthcare facilities is unclear, particularly given the infrequent reporting of HAI and MDRO outbreaks at the national level. Although reporting of microbiological data from local outbreaks to the national level is frequent, transmission of epidemiological data to contextualise with laboratory findings has been relatively sparse, hampering the contextualisation of isolate-level outbreak data, even with its associated metadata. Such integrated data analyses are important to identify potential interventions for outbreaks, and thus important for informing national prevention efforts. An example of strong collaboration was given from prevention for tuberculosis, in which epidemiologists and microbiologists in each Autonomous Region jointly report surveillance data targeted for prevention activities.

Recommendations

- Ensure that hospitals across the country are consistently screening patients for MDRO carriage to reduce the spread of priority MDROs. Such screening is particularly important for control of carbapenem-resistant organisms across borders. Adopt guidance on prevention and control of carbapenem-resistant/multidrug-resistant Gram-negative organisms in healthcare settings from ECDC, WHO, and ESCMID. This involves ensuring:
  - rapid identification of patients who meet the criteria for having a high risk of MDRO carriage;
  - appropriate IPC measures are implemented immediately;
  - screening testing occurs in a timely manner; and
  - appropriate IPC measures are continued during hospitalisation and transfers to other healthcare settings.
- Develop collaborations between Autonomous Regions and scientific societies to facilitate understanding of MDRO control measures taken at the facility level.
- Regularly assess the list of national priority MDROs. Prioritisation of pathogens can be assessed using the criteria, definitions, and levels described in WHO's Bacterial Priority Pathogens List (2024). Continue to consider resistant fungal pathogens, as their importance is highlighted in the WHO fungal priority pathogens list (2022).
- Update the AMR surveillance protocols, considering the possibility of a basic and scalable AMR surveillance with minimum mandatory reporting from all Autonomous Regions. Its aim should be to support the existing and recently established legal frameworks for MDRO surveillance, by strengthening national capacities to identify, investigate and control healthcare outbreaks that are occurring in multiple Autonomous Regions and/or across borders.
- Negotiate an agreement between Autonomous Regions and at the national level for feasible, minimum mandatory reporting, from all Autonomous Regions, of patient-level surveillance data that incorporate both microbiological and epidemiological data, to better understand incidence of priority MDROs. The negotiated agreements should include the pathogens and minimum requirements, in terms of coverage (% population), reporting frequency, metadata, and patient-level data completeness.
- Strengthen engagement with entities that directly engage with healthcare providers and healthcare facilities such as Autonomous Regions, professional/scientific societies, and other national agencies/ministries (for example, the Ministry of Social Affairs and the Ministry of Science, Innovation and Universities (MCIU) to collaborate on IPC work with LTCFs).
- Strengthen collaboration with Autonomous Regions and other stakeholders that engage with healthcare professionals and facilities to ensure epidemiological (patient-based) HAI and AMR data reach the national level to enable identification of issues that require national interventions.

- Reinforce the mechanisms to regularly report national-level laboratory and epidemiological data relating to AMR and HAIs back to data providers.
- Establish additional methods to track progress in engagement with Autonomous Regions relevant to AMR, HAIs and IPC. Indicators might include the number of regions reporting outbreaks per year and/or the number of reported outbreaks per year compared with trends in data from complementary surveillance systems.
- Promote improved national situational awareness for AMR in Spain by increasing the population coverage of the phenotypic AMR surveillance data that are reported annually to ECDC EARS-Net.
- Integrate epidemiological and laboratory data at the local level in the National Surveillance System for informing effective targeted IPC interventions. More detailed and continuously updated data on social, demographic and health information about LTCFs are required. Recipients of supportive IPC 'data for action' initiatives might include regional public health staff, hospital IPC teams, healthcare management, healthcare workers in hospitals and LTCFs, and local teams that provide IPC specialisation training.

Risk communication and community engagement (Capacity 8)

In addition to Risk communication and community engagement (RCCE), the assessment also considered the Infodemic Management (IM) capacity, an area that emerged as of high importance during the COVID-19 pandemic.

Spain is a decentralised country and has a rich capacity to implement RCCE initiatives at regional and local levels. The national level has a good capacity to coordinate inter-regional efforts, especially through the CCAES of the Ministry of Health. Additionally, through the CCAES, the central level has the mechanisms to align with key partners and to support the emergency RCCE activities.

Furthermore, the Ministry of Health's Cabinet of the Minister is working to streamline emergency preparedness and response media relations activities through a strategy that aims to create a network of journalists from central and regional levels that can participate in emergency communication activities in a timely manner.

Nevertheless, Spain's approach towards RCCE-IM at central and decentralised levels is not structured and, though several functions of the capacity are well established and implemented, additional capacity, structure and resources might be beneficial for emergency preparedness and response RCCE-IM interventions.

A key finding is the need for clearly designated human resources to work on RCCE-IM. In case of emergencies, the functions are performed by teams assembled ad hoc, with limited pre-determined roles, responsibilities and coordination. Additionally, there are no RCCE-IM strategies or standard operating procedures during peacetime (i.e. between major outbreak or other events) nor for emergencies, which has the potential to hamper the timely response and coordination of RCCE-IM interventions during an emergency.

Furthermore, the high turnover of staff responsible for communication at central and regional levels, together with lack of permanent designated communication officers at the Ministry of Health or the CCAES, weakens the medium- and long-term capacity of emergency RCCE-IM preparedness and response.

While some RCCE functions are performed within the Ministry of Health and also at regional/municipal levels, there is a gap regarding a coherent, long-term approach to further build on. When specifically assessing IM, no specific activities have been identified at national or decentralised levels for identifying and addressing misinformation, disinformation or false narratives or to manage infodemics that can affect the public health response.

As some of the functions of RCCE are performed in a coordinated and predictable manner within the Ministry of Health in different programmes and departments – e.g. Control Division of HIV, STIs, Viral Hepatitis and TB, with proven positive results in case of emergencies, such as the mpox outbreak in 2022 – this might be extrapolated for RCCE-IM emergency preparedness and response. This regards especially the work of formalising partnerships with civil society organisations and populations at risk, including populations who experience barriers in accessing healthcare services, constantly involving them in the design and implementation of the interventions, keeping them at the centre of the emergency response.

While at regional and municipal levels there are multiple RCCE initiatives and the CCAES, in certain cases, has the central role in coordinating these inter-regional efforts, there are limited options for ensuring transferability and long-term usability of the results of these initiatives by other municipalities and regions. A central repository of such initiatives was created during COVID-19; however, it was discontinued.

While there are available funds/grants to support RCCE-IM initiatives, there is limited predictability regarding the framework or the scope for which funds can be allocated for RCCE-IM at the national level, who can access these funds and for what.

There are strong Behavioural and Cultural Insights (BCI) research capacities to inform RCCE-IM initiatives (e.g. at National Institute of Health Carlos III), including during emergencies; however, a more structured approach towards research can improve targeted and informed RCCE-IM interventions.

It is acknowledged that the team was not able to meet with certain counterparts due to logistical and other limitations. During the discussions with national experts, we identified the Sub-directorate General of health promotion, prevention

and equity from the Ministry of Health as a key stakeholder involved during the early stage of COVID-19 pandemic response in risk communication activities at the national level. Their potential involvement in the response of future public health events was not discussed in detail and further information will be needed to assess their potential role.

Recommendations

- Establish a national RCCE-IM structure: Develop a formalised, structured approach to RCCE-IM at both central and regional levels. This should include clear roles, responsibilities, and intersectoral coordination mechanisms for emergency preparedness and response.
- Include the RCCE-IM pillar in the National Preparedness and Response Plan.
- Create and implement RCCE-IM strategies and standard operating procedures for both non-emergency and emergency situations to improve the timeliness and efficiency of RCCE-IM interventions.
- Allocate dedicated permanent staff for RCCE-IM functions within the Ministry of Health, the CCAES, and/or at regional levels. Ensure clear, pre-defined roles and responsibilities for these staff members, especially during emergencies.
- Invest in ongoing training and capacity-building programmes for RCCE-IM staff at all levels.
- Establish national and regional mechanisms to identify and address misinformation, disinformation, and false narratives.
- Define a clear and predictable mechanism to scale-up in case of need during emergencies. Identify a contact point responsible for RCCE-IM in the Ministry of Health that could serve as the liaison with different groups working in this field at national and regional levels.
- Formalise partnerships with civil society organisations, populations at risk, and those experiencing barriers in accessing healthcare services. Involve these stakeholders consistently in RCCE-IM efforts, and ensure they play a central role in designing and implementing the RCCE-IM interventions.
- Re-establish and maintain a central repository for RCCE-IM initiatives at the national level, ensuring that successful strategies/information campaigns/results of research from central, regional and municipal levels are easily transferred and can be applied across the country, even in non-emergency times.
- Ensure a clear, predictable national/regional framework for RCCE-IM funding, specifying who can access funds and the scope of funding.
- Implement the proposed strategy to create a network of health- and science-specialised journalists at the national and regional levels, ensuring timely and consistent involvement in emergency communication activities. It could also be included in a broader RCCE-IM strategy.
- Include Behavioural and Cultural Insights (BCI) as a structural pillar of the RCCE-IM process, including population feedback and identification of challenges related to behavioural aspects. For this purpose, a more structured approach towards research (including at least medium- to long-term planning) is recommended, including stable and clear communication channels with the Ministry of Health and the CCAES.

Other capacities not assessed in-depth

Policy, legal and normative Instruments to implement the International Health Regulations 2005 (Capacity 1)

Public Health Law 33/2011 is the main legal framework in Spain that lays out the legislative foundation across all administrative levels in Spain for emergency preparedness and response. The new Royal decree for the development of the National Preparedness and Response Plan for Public Health emergencies is under development. It includes aspects related to the Governance and Preparedness and Response capacities to respond to Public Health Emergencies.

In Spain, each regional health authority representing an Autonomous Region has significant control over its own healthcare policies, budgets, and public health human resources and crisis management response. While the national government retains some oversight, particularly in times of national crises, it often faces difficulties in enforcing uniform public health policies across all regions. The public health emergency coordination and response is oriented by consensus between the national and regional authorities, represented in the National regional coordination council.

Despite the legislative framework with public Health Law 33/2011, the decentralised system in Spain leads to variations in how health-related issues – including public health – are managed, although there are mechanisms as the Interregional Council of the National Health System to guarantee cohesion. The fragmented legal authority between the national government, Autonomous Regions and the local level can pose challenges for a unified crisis response; however, as the COVID-19 pandemic has shown, overall Spain is able activate, scale-up and scale-down crisis response in a nationally coherent way through increased coordination efforts.

Despite these challenges, it was noted that Spain has evaluated and reported their IHR implementation and coordination capacity under article 7 and SPAR, as level 4 or 5, except for indicator C.1.2 Gender (SPAR). However, it was recognised that Spain does implement some gender-related activities so this should be better reflected in the next cycle of the self-evaluation and reporting. During the three-year SPAR reporting period, between 2021 and 2023, the fluctuating score under C.1 Legislation was noted, without any further explanation or comments added.

Recommendations

- Use after-action reviews consistently and systematically to review legislative policies and the IHR governance structure. Organisation of after-action reviews could potentially be outsourced to a third-party (e.g. an academic department) to avoid over-burdening the public health staff.
- Plan and organise more systematic simulation exercises across different administrative levels (e.g. between national and regional health authorities) to assess the standardisation of procedures and coordination mechanisms for IHR implementation across all levels.

Financing (Capacity 2)

Before the COVID-19 pandemic, Spain had never faced a national State of Alarm related to a health emergency or one that compromised the supply of essential MCMs. The pandemic, as a global emergency, streamlined the allocation of funds. However, the country already had in place a pre-established budget for health alerts in the framework of contingency plans for emergency response, which allowed for post-event accountability.

In the event of a crisis affecting only Spain, two key financial mechanisms would come into play:

- While Spain operates under a highly regionalised system, during national emergencies the central government has the authority to swiftly borrow and allocate funds as needed to provide financial and logistical support to Autonomous Regions. After the situation is under control, the financial and logistical responsibilities are passed back to the Autonomous Regions.
- In emergencies requiring extraordinary financial support, including for local (regional) crises, Spain operates outside regular legal frameworks through the National Security System, under the Law 36/2015, of 28 September, of National Security. This system enables swift financial response and resource re-distribution.

Besides the availability of emergency response and contingency funds, there is a need to ensure more domestic financing is made available for longer term preparedness and capacity-building activities to enhance health security and strengthen the health system. The pandemic highlighted areas for improvement, especially in the collaboration between central and regional governments; moreover, new frameworks have been put in place to disburse funds more quickly and efficiently.

Recommendations

- Identify and ensure availability of longer-term preparedness/capacity-building funds to utilise domestic financing for strengthening the health system and health security.

Human resources (Capacity 5)

The public health workforce shortage is considered a critical issue at both national and regional levels. Rapid human resource exchange during public health emergencies works on an informal basis, although there are national regulations that are adjusted in case of a public health emergency between the central government and the Autonomous Regions. A strategy is being developed, based on the Zaragoza Declaration (2022), that lays the foundations for the new Public Health Surveillance System; this will include increased capacity of public health personnel during a public health emergency, as well as training and capacity-building. It will be linked to the adoption of the new Royal Decree on preparedness and response to public health emergencies.

Recommendations

- Address workforce surge during public health emergencies, possibly by defining a national emergency for workforce mobilisation following the recognition of a national emergency. This should include:
  - Mapping of the public health and healthcare workforce in different regions;
  - Ensuring that trained professionals can be rapidly deployed during a crisis, as well as plans for workforce capacity-building and well-being;
  - Developing mechanisms for quickly scaling-up the workforce, such as activating reserve personnel, utilising volunteers, or re-allocating staff from non-essential services;
  - Detailing how the legal framework will facilitate rapid data collection and analysis to identify workforce needs, as well as intra-national resource allocation based on available resources during a crisis.
- Make efforts to encourage adequate staffing for disease surveillance, preparedness, and response within the Autonomous Regions.
- Establish a programme for capacity-building prior to a public health emergency: Develop and implement a comprehensive training programme for professionals across Autonomous Regions, with a specific focus on managing public health emergencies. This should include scenario-based exercises, cross-regional collaborations, and rapid deployment strategies for addressing surges in demand for human resources.
- Solidify the ability to quickly adopt the existing civil protection mechanism to enhance coordination and resource-sharing between regions, including public health human resources. Establish clear communication channels and protocols to quickly mobilise human resources and equipment to areas experiencing higher demand.
- Continue to prioritise the sustainability of the public health workforce by implementing policies and investments that support long-term workforce development. This also presents an opportunity to address underlying

workforce shortages while promoting equitable workforce distribution and ensuring that all professionals, including those outside of the health sector, are recognised for their contributions to public health.

Health service provision (Capacity 7)

Health services are managed at the Autonomous Region level. A legal framework for national coordination of health service provision in the setting of health emergencies is under development, in which the 'Comite Asistencial' is intended to be created. The development of a platform for healthcare services monitoring is included in the proposal.

Recommendations

- Ensure the development and implementation of the National Plan for healthcare continuity, including patient referrals and resource sharing in and between the Autonomous Regions. Define and clarify the role of national authorities in interdisciplinary crisis management under the new National Preparedness and Response Plan to ensure smooth coordination between sectors (including laboratory services, public health services, critical care services, and long-term care facilities).
- Ensure the creation of a platform for real-time monitoring of healthcare services to better track capacity and availability during public health emergencies. Such a platform should be rapidly deployable to obtain data in a timely manner. Use of this ad-hoc crisis response monitoring system should be incorporated into trainings and simulated exercises.
- Explore the legal framework to map healthcare service capacity, even outside emergency situations, for better preparedness and for obtaining and implementing hospital alert and response plans, ensuring rapid action during emergencies

Formalise agreements with neighbouring countries to ensure provision of healthcare services, when needed.

Points of Entry and border health (Capacity 9)

It was recognised that Foreign Health (FH) under the Ministry of Health is the competent authority responsible for IHR and EU regulations at Points of Entry (PoE) and that 28 FH units at PoE are responsible for managing and coordinating emergency preparedness and response at PoE. FH works closely with the CCAES when facing a public health event at PoE and serves as a link between the PoE staff and the NFP for the IHR.

Spain has eight designated ports, five designated airports and zero designated ground crossings. Consequently, there is limited assessment of the capacities at the ground crossings/EU external borders with Morrocco, Ceuta and Melilla autonomous cities, to respond to public health emergencies. Nevertheless, there are two FH units located at Ceuta and Melilla that are responsible for assessing and responding to events that could happen at those borders. [5]

FH has clearly established standard operating procedures in place for PoE stakeholders in emergency response operations. These procedures have been sufficiently integrated into the existing contingency and emergency response plans that are available at PoE, instead of creating additional plans, to avoid confusion and potential duplication.

Spain has a regular and systematic Simulation Exercise (SimEx) programme that specifically tests public health response operations at PoE. This is a great example of how SimEx can be used in a more comprehensive manner that benefits PoE functions, although it was not particularly clear if the exercises' scopes include testing international travel-related measures.

Recommendations

- Expand the PoE SimEx programme to specifically test international travel-related measures and include other sectors and stakeholders outside the public health domain, including customs/border protection, agriculture, animal health (vets), tourism, private sector transport companies, etc.
- Include designated airports in the PoE SimEx programme as airports function quite differently compared with ports, and the aviation industry is less familiar with public health procedures and PoE standard operating procedures.
- Strengthen cross-border cooperation with non-EU countries like Morocco, for the ground crossing in the autonomous cities of Ceuta and Melilla.

Zoonotic diseases and threats of environmental origin, including those due to the climate (Capacity 10)

Spain has a mechanism for collaboration and coordination between public health and animal health sectors. It seems to work well with mutual notification of relevant events, timely information sharing during outbreak investigation and, to some extent, conducting joint activities such as risk assessments. However, this collaboration is primarily person-based and has no systematically standardised procedures, although information is also shared

[5] It was noted that reporting under Article 7 (A9.1) and under SPAR (C11.2) on contingency plans at designated PoE is inconsistent due to the fact that the Article 7 question A9.1 does not have the N/A option. As Spain does not have an official designated ground crossing, as per the IHR (2005), level 2 was chosen for this indicator even though N/A would be applicable in this case.

through generic email addresses. This might be a challenge when there is a high turnover of staff or when the perception of risk or priorities regarding an event are not in line between the different sectors involved.

The animal health sector has a platform (Sistema de Alerta Sanitaria Veterinaria (RASVE)) that the human health sector also has access to. It is used for information sharing from the animal to the human sector. This was identified as good practice that facilitated the communication between sectors and could be potentially extended to develop a platform for structured information sharing between human, animal and environmental sectors.

The need to strengthen and define partnerships and joint activities in peacetime, which can then be implemented and used during public health emergencies, was discussed. An example of one such specific activity was the collaboration between animal and human laboratories during the COVID-19 pandemic. In this instance, the animal health laboratory network was offered to be used for human health diagnosis, but it was not possible to use it consistently across the country. Having a process defined in advance to use laboratories from other sectors during emergencies could have facilitated their use in this situation. The decision-making process to implement actions that might impact the animal and human sectors are taken separately by the corresponding bodies. This is also an example of an activity that could benefit from a joint procedure, at least for discussing the measures and their cross-sectoral impact.

The collaboration between the environmental sector, led by the Ministry of Ecological Transition and the Demographic Challenge (Ministerio para la Transición Ecológica y el Reto Demográfico (MITECO)) and the animal health sector, led by the Ministry of Agriculture, Fisheries and Food (Ministerio de Agricultura, Pesca y Alimentación (MAPA)) seems to be in place and functioning. The collaboration between the human health sector, led by the Ministry of Health (Ministerio de Sanidad), and the environmental sector appears to be more limited. A collaboration exists between the MITECO and the specific environmental units in the Ministry of Health, but is not extended to the crisis management team at the CCAES or other structures within the Ministry of Health.

A Health and Environment Strategic Plan, developed by the Ministry of Health with the collaboration of different sectors, is in place in the country. Fourteen areas of action are defined and the bodies responsible for implementing the different milestones are assigned, even if not reflected in the generic plan. The implementation of the plan is monitored by the Ministry of Health. The activities are funded by different ministries in the country and the budget is not always secured. This difference in budget source might cause inequalities in the implementation of the plan.

Recommendations

- Translate the good collaboration mechanisms between human and animal health into plans, guidelines or standard operating procedures to make sure this communication is sustained over time and not person dependant. Operational procedures, such as the ones existing for food- and waterborne diseases, could be extended to other disease groups.
- Test preparedness activities and joint processes during small events that can then be utilised or replicated during large-scale outbreaks (e.g. joint training, protocol for animal/human lab support, WGS approach to surveillance, etc.). This can facilitate the implementation of a One Health approach during crisis response. Some specific examples would be to increase the opportunities for multi-sectoral One Health trainings, develop a common platform for information sharing between sectors for outbreak investigation and response activities, or develop protocols to share resources, such as the laboratory networks, during emergencies.
- Strengthen the involvement of the environmental sector in One Health activities. This would include:
  - Involving the environmental sector in activities outside outbreaks, in the response planning phase or in small-scale outbreaks;
  - Having a clear collaboration mechanism between sectors and ensuring business continuity;
  - Identifying an operational/department focal point in each sector involved, e.g. MITECO, MAPA (already identified) and the Ministry of Health.
- Secure funding for harmonised implementation of the environmental plan.

Chemical events (Capacity 11)

In line with the Serious cross-border threats to health Regulation, the preparedness for chemical threats in Spain covers different incidents, like those arising from potential releases from large chemical industrial plants, which is regulated by the Royal Decree 1196/2003 on control and planning by Civil Protection for the risk of serious accidents involving hazardous materials (Real Decreto 1196/2003, de 19 de septiembre, por el que se aprueba la Directriz básica de protección civil para el control y planificación ante el riesgo de accidentes graves en los que intervienen sustancias peligrosas). This document prescribes the preparation of Special External Emergency Plans for each of the large industries that require it, which are approximately 200.

In compliance with the EU Seveso directive, an updated register of companies that are at risk of chemical incidents (Base Nacional de Datos sobre Riesgo Químico (BARQUIM)) has been established; in this database, the companies are registered by using the model indicated by the EU directive.

The risk assessment and management for chemical threats in Spain is in the remit of the Civil Protection:

- At the regional level, the Autonomous Regions have established civil protection emergency plans to mitigate the impact on human health in the event of major accidents involving releases of hazardous substances from large chemical industries located in their territories, upon threat identification and risk assessment.
- At the national level, the Dirección General de Protección Civil y Emergencias, under the Ministry of Interior, has set up a General Civil Protection Emergency Plan (PLEGEM), approved by the Resolution of 16 December 2020, to support the regional plans when needed, and to establish organisational and operational procedures for state resources and services in the event of chemical accidents with national impact.

In these frameworks (regional and national), the Ministry of Health provides expertise in health risk assessment of threats originating from chemicals.

The control measures for chemicals that could be used to produce chemical weapons, as well as for the facilities or equipment that could be used for their production, is regulated in the national legislation (National law 49/1999 on control measures of chemical substances for the development of chemical weapons). A more recent document, the Royal Decree 78/2019, implements the law 49/1999 and includes a list of controlled substances.

The prevention of and the response to terrorist attacks, including any potentially involving the intentional release of chemicals, is covered by a national plan (Plan de Prevención, Protección y Respuesta Antiterrorista (PPPyRA)), approved by the Instruction No. 2/2022 from the Secretary of State for Security (restricted for security reasons). In the event of a terrorist attack involving chemicals, the Ministry of Health is included in the coordination of the incident together with other relevant institutions.

Recommendations

- Develop an operational plan/protocol linking the actions performed by civil protection and public health response in the event of a chemical event.
- Test the protocol together with the other involved partners to identify possible gaps and areas of improvement (e.g. via a SimEx or a command post exercise).
- Revise the plan and include lessons learned from simulations and any potential real incidents involving chemical substances.

Union level coordination and support functions (Capacity 13)

All the Union level coordination and support functions that ensure the health response to a public health emergency at the national level is in coordination with the EU level are present.

The national HSC representatives contribute to the elaboration of the HSC opinions and Commission guidance, and those are then considered for the review of the national plans and the management of public health crises.

The CCAES ensures the interoperability between national public health EOC/IMS and EWRS, ensuring the continuous communication, in case of a public health emergency.

Recommendations

- Reinforce intersectoral collaboration at the national level by ensuring that the new National Preparedness and Response Plan for public health emergencies' scope takes an all-hazards approach and supports the exchange of alerts and response measures with the EU level through the relevant EU alert and information systems, such as EWRS, iRASFF, ADIS, Safety Gate, EW-NPS, CECIS 2.0 and ECURIE.
- Strengthen dissemination of EC recommendations, including HSC opinions and ECDC recommendations, to the regional authorities and inter-sectorial partners.

Research development and evaluations to inform and accelerate emergency preparedness (Capacity 14)

Spain has strong expert institutions and networks capable of conducting operational research, clinical trials and cohort studies that can provide answers to key questions in emergency situations. The Spanish National Research Council (CSIC) has established a Scientific Advisory Committee on Disasters and Emergencies to facilitate provision of expert advice and scientific and technical assistance to public administrations in crisis situations. The committee focuses on preparedness, rapid activation, and coordination. The Global Health Interdisciplinary Platform, coordinated by CSIC, provides solutions for collaboration between multidisciplinary research groups on topics related to infectious disease prevention and control, such as pathophysiology of the disease, containment measures, treatment options, and social and economic impact.

By being one of the main funding agencies for biomedical research, the Instituto de Salud Carlos III (ISCIII) coordinates the national health system research in Spain. Operational research is also ongoing within ISCIII, with activities in areas of epidemiological surveillance, biomedical research, and public health training. However, it has been suggested that developing specific protocols may improve timeliness of operational research for emerging threats; for example, addressing relevant knowledge gaps to allow for early estimates to support timely decision-making regarding public health and social measures and MCMs (e.g. context transmissibility, severity, vaccine effectiveness, etc.).

Resources for research during public health emergencies, including funding, appear to be secured and deployed in the medium term after the start of an event. Ensuring there are resources for outbreak-related research that can be activated within the first days or weeks after the identification of an outbreak was identified as a challenge.

Other processes were identified as a barrier to implement outbreak-related research, such as timely ethical approval. Time required for ethical approval to conduct research during emergencies is substantially shortened compared with regular research projects; however, there is no specific process in place to ensure rapid ethical clearance during emergencies. For certain specific research topics (i.e. vaccination), ethical approval was identified as a key challenge.

Recommendations

- Further document mechanisms and procedures regarding how research and innovation can be integrated into emergency response. This could be included in the forthcoming National Preparedness and Response Plan or in one of the operational plans.
- Define mechanisms for funding critical research activities during crises and ensure removal of any remaining barriers to allow for activation of such activities, including rapid ethical approval for research studies to address critical knowledge gaps (e.g. transmissibility in context, severity, etc.). This is especially important for emerging and re-emerging threats, to inform timely decision-making regarding public health and social measures and MCMs.
- Establish well-defined roles and communication mechanisms between the relevant bodies to enable coordination between research institutions and public health services. This is crucial to avoid overlap and ensure key research is activated in response to an emergency. For preparedness purposes, it would be beneficial to map experts and institutions capable of performing critical research.

Recovery elements (Capacity 15) and Actions taken to improve gaps found in the implementation of prevention, preparedness, and response plans (Capacity 16)

As regards the evaluation of response to the recent COVID-19 pandemic, the CCAES monitored the incidence of reported cases in the country to guide the implementation of public health and social measures. In an ad hoc collaboration with modelling experts, they also evaluated the implemented public health and social measures in all Autonomous Regions in retrospect. In addition, stakeholders from ISCIII are working in the context of an EU-funded project (Be-Ready) to define the best methods for monitoring and evaluating public health and social measures in health emergencies and pandemics.

A national level whole-of-government evaluation was also undertaken, and the new Strategy for Public Health Security in Spain was developed based on the experience of the response to the COVID-19 pandemic, while some aspects are also considered in the National Preparedness and Response Plan under development.

Recommendations

- Include a section on recovery in the forthcoming National Preparedness and Response Plan, including who would be responsible for initiating recovery activities and address findings.
- After completion and adoption of the National Preparedness and Response plan, it is recommended that the MoH, in collaboration with the appropriate stakeholders:
  - ensure the integration and revision, as needed, of the specific operational response plans addressing the different hazards and
  - develop an agreed exercise plan for health preparedness. Simulation exercises can be different types and levels from discussion-led sessions with a narrow focus to large national multisector exercises.

Conclusions

This assessment was conducted in a collaborative environment with active engagement from a diverse set of stakeholders. This approach provided a comprehensive perspective on Spain's current preparedness and response capacities within its decentralised health system. The constructive discussions during the assessment allowed the assessment team to identify strengths and highlight key areas for improvement, resulting in several targeted recommendations that aim to enhance Spain's public health capabilities.

Overall, the assessment revealed that Spain has a solid foundation of collaboration between the Ministry of Health and the Autonomous Regions, supported by ongoing legislative developments such as the National Preparedness and Response Plan for Public Health Threats and the framework for the National Public Health Agency. These initiatives are expected to strengthen Spain's legal and operational frameworks for emergency preparedness. However, sustained effort is needed to formalise and optimise collaboration mechanisms across regional and national levels, ensuring that public health resources and communication pathways are equipped to respond effectively in emergencies.

To translate the assessment findings into actionable improvements, Spain will need to mobilise further commitment and resources at both the regional and national levels. By implementing the recommendations outlined in this

report, Spain can solidify its preparedness infrastructure and foster a more coordinated response to future public health emergencies.

Annex 1. List of capacities included in the assessment

Table 1A. List of capacities included in the assessment

Capacity no.	Capacity name
Capacity 1.	International Health Regulation (IHR) implementation and coordination
Capacity 2.	Financing
Capacity 3.	Laboratory
Capacity 4.	Surveillance
Capacity 5.	Human resources
Capacity 6.	Health emergency management
Capacity 7.	Health service provision
Capacity 8.	Risk communications and community engagement (RCCE)
Capacity 9.	Points of Entry (PoEs) and border health
Capacity 10.	Zoonotic diseases and threats of environmental origin, including those due to the climate
Capacity 11.	Chemical events
Capacity 12.	Antimicrobial resistance (AMR) and healthcare-associated infections
Capacity 13.	Union level coordination and support functions
Capacity 14.	Research development and evaluations to inform and accelerate emergency preparedness
Capacity 15.	Recovery elements
Capacity 16.	Actions taken to improve gaps found in the implementation of prevention, preparedness and response plans

Annex 2. Practical arrangements for the assessment process

This Annex describes the main practical arrangements made before the Public Health Emergency Preparedness Assessment (PHEPA), under Article 8 of the Regulation (EU) 2022/2371 on serious cross-border threats to health, in Spain. The country visit to Spain took place from 14 to 18 October 2024 at the Ministry of Health in Madrid.

This section identifies the experts that were members of the assessment team and the national experts that participated in the assessment.

Assessment team

The assessment team was composed of:

- One team leader from ECDC;
- One expert per in-depth capacity;
- Experts from relevant Union agencies and bodies.

Upon country acceptance, experts were also included from:

- WHO Regional Office for Europe;
- One expert from Portugal.

Experts from the Directorate-General for Health & Food Safety and the Health Emergency Preparedness and Response Authority of the European Commission also joined to support the assessment as subject matter experts. They were engaged solely in the capacities within their areas of expertise, and their access to data was restricted to the information essential for their tasks.

Table 2A. Members of the assessment team

No.	Name	Institution (ECDC/WHO/EU agencies and bodies, Commission services, other countries)	Role in the team (team leader/ expert)	Leading and supporting capacities
1	Thomas Hofmann	ECDC	Team lead	• IHR • Union level coordination • PoEs and border health
2	Pete Kinross	ECDC	Expert	• AMR and HAIs • Laboratory • Surveillance • Health Service Provision
3	Vivian Leung	ECDC	Expert	• AMR and HAIs • Laboratory. • Surveillance • Human Resources • Health Service Provision
4	Daniel Palm	ECDC	Expert	• Laboratory • Surveillance • AMR and HAIs • Research development and evaluations to inform and accelerate emergency preparedness
5	Laura Espinosa	ECDC	Expert	• Surveillance • Zoonotic diseases • AMR and HAIs

6	Agoritsa Baka	ECDC	Expert	• Health Emergency Management • Zoonotic diseases • Chemical events • Recovery elements • Actions taken to improve gaps in PPR
7	Adriana Romani	ECDC	Expert	• Zoonotic diseases • RCCE • Research development and evaluations to inform and accelerate emergency preparedness
8	Catalin Bercaru	ECDC	Expert	• RCCE • Financing • Human Resources
9	Orlando Cenciarelli	ECDC	Expert	• Chemical events • Health Emergency Management • Financing • Recovery elements • Actions taken to improve gaps in PPR
10	Maryoli Veloso Fraigola	ECDC	Expert	• Health Emergency Management • Recovery elements • Research development and evaluations to inform and accelerate emergency preparedness
11	Cinthia Menel Lemos	DG SANTE	Expert	• Union level coordination • IHR. • Health Emergency Management
12	Dina Ashour	DG HERA	Expert	• Health Emergency Management • MCM
13	Vasco Ricoca Peixoto	Country Expert	Expert	• Surveillance • Laboratory • Actions taken to improve gaps in PPR • Research development and evaluations to inform and accelerate emergency preparedness
14	Frederik Anton Copper	WHO Euro	Expert	• Health Emergency Management • IHR • PoEs and border health

Table 3A. National experts participating in the assessment process

Name	National institution	Role in the assessment	Main capacity to assess (related to the assessment capacities)
María José Sierra Moros	CCAES	Moderator	• Health Emergency Management • Surveillance
Berta Suárez Rodríguez	CCAES	Moderator	• Health Emergency Management • Zoonotic diseases • Chemical Events
Sonia Fernández Balbuena	CCAES	Expert	• Surveillance • Laboratory
Bernardo Guzmán Herrador	CCAES	Expert	• Health Emergency Management
Lucía García San-Miguel	CCAES	Expert	• AMR and HAIs
Esteban Aznar Cano	CCAES	Expert	• Zoonotic diseases • AMR and HAIs • Laboratory
Alejandro Ciriano Cervantes	CCAES	Expert	• Risk Communication and Community Engagement
Fernando Riesco-Rodríguez	Subdirección General de Sanidad Exterior, Ministerio de Sanidad	Expert	• Points of Entry
Miguel Dávila-Cornejo	Subdirección General de Sanidad Exterior, Ministerio de Sanidad	Expert	• Points of entry
José L Peñalvo	CNE-ISCIII	Expert	• Surveillance
Rosa Cano Potreros	CNE-ISCIII	Expert	• Surveillance • Communicable diseases
Carmen Varela Martinez	CNE-ISCIII	Expert	• Surveillance • Communicable diseases • AMR • Zoonotic diseases
Susana Monge	CNE-ISCIII	Expert	• Surveillance – National coordinator of respiratory virus surveillance
Miguel Calero Lara	ISCIII	Expert	• Public Health Structure • Research and Planning
Mª Belén Aracil García	CNM-ISCIII	Expert	• AMR and HAIs • Surveillance
Mª José Buitrago Serna	ISCIII	Expert	• Research • Planning • Laboratory
Isabel Jado García	CNM-ISCIII	Expert	• Laboratory • Zoonotic diseases • Director, CNM
Inmaculada Casas Flecha	CNM-ISCIII	Expert	• Assessment of cross-cutting aspects • OFP respiratory virus laboratory
Juan Emilio Echevarría Mayo	CNM-ISCIII	Expert	• Health Emergency Management (Rapid Response Unit)
Mª Dolores Fernández García	CNM-ISCIII	Expert	• Laboratory
Silvia García Cobos	CNM-ISCIII	Expert	• AMR and HAIs

Horacio Gil Gil	CNM-ISCIII	Expert	• Laboratory
Silvia Herrera León	CNM-ISCIII	Expert	• Surveillance • Zoonotic diseases • Environmental (OFP Enterobacteria's Laboratory)
Laura Herrera León	CNM-ISCIII	Expert	• AMR and HAIs
Emilia Mellado Terrado	CNM-ISCIII	Expert	• AMR and HAIs
Mª Dolores Pérez Vázquez	CNM-ISCIII	Expert	• AMR and HAIs Laboratory
Mª Paz Sanchez Seco	CNM-ISCIII	Expert	• Zoonotic diseases • environmental
Sonia Vázquez Morón	CNM-ISCIII	Expert	• Laboratory • Surveillance
Yolanda Vega Rocha	RELAB-ISCIII	Expert	• Health Emergency Management (RELAB)
Óscar Zaragoza Hernández	CNM-ISCIII	Expert	• AMR and HAIs
Margarita del Val Latorre	CSIC	Expert	• Research on Global Health, infectious diseases and vaccines
Diego Ramiro Fariñas	CSIC	Expert	• Research on Social sciences and Demographics
Ana Allende Prieto	CSIC	Expert	• Research on health risks, food and water safety and wastewater-based epidemiology
Isabel Muñoz Machín	Instituto Nacional de Gestión Sanitaria, Ministerio de Sanidad	Expert	• Emergency logistic and supply chain management
Javier López Pérez	Instituto Nacional de Gestión Sanitaria, Ministerio de Sanidad	Expert	• Emergency logistic and supply chain management
Inés Moreno Pardos	Instituto Nacional de Gestión Sanitaria, Ministerio de Sanidad	Expert	• Emergency logistic and supply chain management
Yolanda Pascual Fontanillo	Instituto Nacional de Gestión Sanitaria, Ministerio de Sanidad	Expert	• Emergency logistic and supply chain management
Maria José Calvente Cestafe	Instituto Nacional de Gestión Sanitaria, Ministerio de Sanidad	Expert	• Emergency logistic and supply chain management
Antonio López Navas	Agencia Española de Medicamentos y Productos Sanitarios	Expert	• AMR and HAIs
Manuel Ibarra Llorente	Agencia Española de Medicamentos y Productos Sanitarios	Expert	• Emergency logistic and supply chain management
Esther Cobo García	Agencia Española de Medicamentos y Productos Sanitarios	Expert	• Emergency logistic and supply chain management
Rubén Sandé Rodríguez	Dirección General de Protección Civil (Ministerio Interior)	Expert	• Health emergency management
Carlos García Vega	Dirección General de Protección Civil (Ministerio Interior)	Expert	• Health emergency management
David García Rivas	Secretaría General Técnica, Ministerio de Sanidad	Expert	• Policy, legal and normative Instruments to implement the International Health Regulations (IHR) 2005

Natalia Las Heras	Secretaría General Técnica, Ministerio de Sanidad	Expert	• Policy, legal and normative Instruments to implement the International Health Regulations (IHR) 2005
Rosalía Fernandez Vázquez	Subdirección General de Formación y Ordenación Profesional, Ministerio de Sanidad	Expert	• Human resources
Tania Cedeño Benavides	Subdirección General de Formación y Ordenación Profesional, Ministerio de Sanidad	Expert	• Human resources
Begoña Brime Beteta	Observatorio Español de las Drogas y las Adicciones	Expert	• Health emergency management
Margarita Palau	Subdirección General de Sanidad Ambiental y Salud Laboral, Ministerio de Sanidad	Expert	• Health emergency management
Esperanza Guevara Alemany	Subdirección General de Sanidad Ambiental y Salud Laboral, Ministerio de Sanidad	Expert	• Health emergency management
Laura Gómez Gonzalez	Subdirección General de Sanidad Ambiental y Salud Laboral, Ministerio de Sanidad	Expert	• Health emergency management
Esther Martín de Dios	Subdirección General de Sanidad Ambiental y Salud Laboral, Ministerio de Sanidad	Expert	• Health emergency management
Raquel Fernández	Subdirección General de Sanidad Ambiental y Salud Laboral, Ministerio de Sanidad	Expert	• Health emergency management
Carlos Bellón	Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)	Expert	• Health emergency management
Francisco Jiménez	Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)	Expert	• Health emergency management
Miguel Ángel Barrado Morín	Ministerio del Interior	Expert	• Health emergency management
Juan Antonio Belinchón	Ministerio del Interior	Expert	• Health emergency management
Yolanda Pérez	Consejería de Sanidad, Comunidad Autónoma de Canarias	Expert	• Risk Communication and Community Engagement
Nicola Lorusso	DG Salud Pública, Comunidad Autónoma de Andalucía	Expert	• Health emergency management – regional level
Jacobo Mendioroz	DG Salud Pública, Comunidad Autónoma de Catalunya	Expert	• Health emergency management – regional level
Teresa Montserrat Rubio Sánchez del Valle	Asesora del Gabinete de Prensa, Ministerio de Sanidad	Expert	• Risk Communication and Community Engagement
Julia del Amo	División de Control de VIH, ITS, Hepatitis Virales y Tuberculosis	Expert	• Risk Communication and Community Engagement
Ana Belén Aguilar	Consejería de Salud y Consumo, Comunidad Autónoma de Andalucía	Expert	• Risk Communication and Community Engagement – regional level
Fernando Borredá	Ministerio de Industria y Turismo	Expert	• Health emergency management • Emergency logistic and supply chain management
María Yagüe	Ministerio de Industria y Turismo	Expert	• Health emergency management • Emergency logistic and supply chain management

Nuria Prieto	Subdirección General de Calidad Asistencial	Expert	• AMR and HAIs
Rebeca Padilla	Subdirección General de Calidad Asistencial, Ministerio de Sanidad	Expert	• AMR and HAIs
Pilar Aparicio	Subdirección General de Calidad Asistencial, Ministerio de Sanidad	Expert	• AMR and HAI
Alejandro Zamanillo	Ministerio de Defensa	Expert	• Emergency logistic and supply chain management
Loreto Gutiérrez Hurtado	DSN	Expert	• Emergency logistic and supply chain management

Table 4A. Agenda for the in-country visit

	14 Oct	15 Oct	16 Oct	17 Oct	18 Oct
	Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
8:30	Welcome & Registration	Registration	Registration	Registration	ECDC assessment team preparation for the closing session. Agree on slides with key findings and recommendations. (Room available at the MoH)
9:00	Opening Remarks (Assessed country)	C.2 Finance, C.5 Human Resources and C.7 Health Service Provision	ROOM 1: Laboratory ROOM 2: Health Emergency Management ROOM 3: RCCE	ROOM 1: AMR and HAIs ROOM 2: Health Emergency Management ROOM 3: RCCE	
9:30	Overview and key aspects of the assessment process (ECDC)				
10:00	Overview of the country public health structure and preparedness and response mechanisms in the country (1) (Assessed country) PUBLIC HEALTH STRUCTURE				
10:30	Break	Break	Break	Break	Registration
11:00	Overview of the country public health structure and preparedness and response mechanisms in the country (2) (Assessed country) PLANNING AND INTERACTIONS BETWEEN ALL THE PLANS	C.9 PoE and C.11 Chemical events	ROOM 1: Laboratory ROOM 2: Health Emergency Management ROOM 3: RCCE	ROOM 1: AMR and HAIs ROOM 2. Health Emergency Management ROOM 3: RCCE	Main Findings and Conclusions (ECDC)
11:30					Recommendations and Next Steps (ECDC presentation and discussion with assessed country)
12:00	Assessment of Cross-Cutting Aspects				
12:30	Lunch	Lunch	Lunch	Lunch	Lunch
13:00					
13:30	Assessment of Cross-Cutting Aspects	C.10 Zoonotic diseases and environmental	ROOM 1: Surveillance ROOM 2: Health Emergency Management ROOM 3: RCCE	ROOM 1: Discussion: ECDC with experts from C3, C4 and C12 ROOM 2 and 3: To be assessed: the need to have a wrap-up session between experts from C6 and C8	Debrief on the ECDC assessment process (structure, preparation, organisation).
14:00					Placeholder for continued debriefing/ debriefing with senior national representatives
14:30	Non in-depth C.1 IHR and C.13 Union level coordination				Concluding Remarks (Assessed country)
15:00	Break	Break	Break	Break	
15:30	Non in-depth C.1 IHR and C.13 Union level coordination	C.14 Research	ROOM 1: Surveillance 2. Health Emergency Management 3. RCCE	C.15 Recovery and C.16 Action plan, SIMEX, AAR	
16:00					
16:30					
17:00	Wrap-up Day 1 (ECDC together with assessed country)	ECDC assessment team wrap-up day 2	Wrap-up day 3 (ECDC together with assessed country)	ECDC assessment team wrap-up day 4 Start preparing for the closing session	
17:30	ECDC assessment team wrap-up day 1		ECDC assessment team wrap-up day 3		
18:00					

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