

TECHNICAL REPORT



The EU experience in the first phase of COVID-19: implications for measuring preparedness

ECDC TECHNICAL REPORT

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Abbreviations

COVID-19	Coronavirus disease 2019
FAO	The Food and Agriculture Organization of the United Nations (FAO)
GHSI	Global Health Security Index
GP	General Practitioners
HEPSA	Health Emergency Preparedness Self-assessment
JEE	Joint External Evaluation
NFP	National focal points
OIE	The World Organisation for Animal Health
PHEP	Public Health Emergency Preparedness
PHEIC	Public Health Emergency of International Concern
QMS	Quality World Animal health information system management system
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
WHO	World Health Organization
WAHIS	World Animal Health Information System

Executive summary

In light of challenges experienced in the COVID-19 crisis, there has been a review of the European Union (EU) legislation to strengthen the EU's collective preparedness to respond to communicable disease threats in the future. The Decision 1082/2013/EU for serious cross border health threats is revised into a Regulation, which is to be adopted in the autumn of 2022. The ECDC mandate is also revised and will enter into force once the Regulation for serious cross border health threats is adopted and published in the EU official journal. The measurement and assessment of the performance of public health emergency preparedness (PHEP) systems is a key component to the process of strengthening preparedness.

This technical report presents an analysis focusing on three issues (testing and surveillance, healthcare sector coordination, and emergency risk communication) during the first phaseⁱ of the COVID-19 pandemic. The analysis identifies specific challenges that were experienced in this phase, as well as successful responses to them. The implications for measuring preparedness are also identified in order to inform outbreak preparedness efforts in the EU Member States in the future.

This analysis is based on the experiences of five countries (Croatia, Finland, Germany, Italy and Spain) during the first phase of the pandemic, i.e. before the initiation of vaccination programs in December 2020. It draws on: a) pandemic preparedness and response plans, standard operation procedures and other documents related to COVID-19 response measures provided by the countries, b) interviews of country representatives, and c) other literature identified through the conduction of rapid literature reviews.

The analysis identifies the following overarching issues with existing measurement systems for preparedness:

- The COVID-19 pandemic required EU Member States to develop new strategies, approaches and policies related to their PHEP systems and structures under pressure. These also had to be reviewed and revised as the pandemic evolved. The extent of revision and innovation required was not contemplated in existing measurement tools for preparedness.
- Existing measurement tools for preparedness are generally not consistent with a country's internal hierarchical structure of public health, healthcare, and other entities that influence emergency responses.
- Existing measurement tools for preparedness generally do not reflect the required coordination among different sections of the healthcare system, particularly at the hospital and community-based levels.
- Existing measurement tools for preparedness generally do not allow for adequate flexibility and resilience required to address the challenges of scaling up a country's pandemic response.

Section 3.1 builds on these overarching themes with specific indicators of issues missing from, or not adequately covered in existing preparedness measurement systems, particularly, the ECDC Health Emergency Preparedness Self-assessment (HEPSA) tool and the WHO Joint External Evaluation (JEE) tool, and for some parts, the Global Health Security Index (GHSI). The following conclusions are arrived at:

- An indicator should be included in the measurement tools for preparedness referring to the ability to conduct testing at scale which was critical in the early phase of the pandemic.
- An indicator for surveillance system flexibility should be introduced in the measurement tools for preparedness.
- In fact, the existing measurement tools for preparedness related to testing and surveillance cover the main tasks but do not address the ability of systems to scale up testing capacity, the importance and complexity of sub-national structures for surveillance and epidemiological investigation, or the challenges of adapting existing surveillance systems and developing new ones during the pandemic. These need to be addressed with accurate indicators.
- Although three capabilities in the ECDC PHEP logic model (management of medical countermeasures, supplies and equipment; medical surge; and hospital infection-control practices) proved to be critical, they are not represented with respective indicators in existing measurement tools for preparedness.
- The ECDC PHEP logic model 'preventive services' capability should include a new broader capability on the 'coordination of population-based medicine', defined as 'the ability to activate and strengthen coordination at a given geographical territory – during an outbreak of a high impact infectious disease – public health, outpatient care, including primary care services, mental health and social support agencies, public and private sector and inpatient health care, using integrated pathways between different levels of care (out- and in-patient).'

ⁱ The first phase is defined as the period in 2020, prior to the introduction of vaccines against SARS-CoV-2.

- The experience during the response to COVID-19 proved that the risk communication capabilities identified in the ECDC PHEP logic model are valid and relevant, but are not completely represented in the existing measurement tools for preparedness. In addition, countries experienced difficulties in managing an epidemic of information, which meant that the logic model should be further expanded to include a fifth capability, 'infodemic management', i.e. dealing with an overabundance of information (some accurate and some not).

In summary considering different existing preparedness measurement systems, the analysis in this report suggests that the type of measurement approach and the format utilised in the Joint External Evaluation process, for example, might be useful in the assessment of the EU's preparedness efforts. This would involve first developing a set of measurement tools and indicators to address the areas identified in the analysis as not so well developed, and then to create a scoring system or scale for each domain. As with the JEE process, the assessment would begin with an analysis and a preliminary scoring by national experts. This would be followed by a meeting in which peers from other countries review documentation from the internal analysis and meet with national experts to achieve consensus about scoring. The evaluation process could include an analysis of existing systems, performance during the COVID-19 pandemic, and the 'stress tests' mentioned in proposed EU legislation on health emergency preparedness and response.

1 Introduction

At the European Union (EU)-level, effectively responding to emerging public health threats requires a strong national strategy as well as effective coordination across countries. In 2013, the European Union (EU) adopted 'Decision No. 1082/2013/EU of the European Parliament and of the Council', which seeks to strengthen public health emergency preparedness (PHEP) and response planning within and across EU Member States. [1] Currently, in light of challenges experienced in the COVID-19 crisis, this legislation has been reviewed to strengthen both EU and the Member States' collective ability to respond to communicable disease threats in the future [2].

Public health emergency preparedness has been defined as, 'the capability of the public health and healthcare systems, communities, and individuals, to prevent, protect against, quickly respond to, and recover from health emergencies, particularly those whose scale, timing, or unpredictability threatens to overwhelm routine capabilities. Preparedness involves a coordinated and continuous process of planning and implementation that relies on measuring performance and taking corrective action' [3].

Preparedness, thus, is not a simplistic answer to the common question 'Are we prepared?', rather, it is a process in which assessing the performance of PHEP systems is a key component. As both public health emergencies and the systems that respond to them are complex in nature (as described in the following sections), applying measurement tools and indicators for preparedness has its own challenges.

With more than 610 million people infected and six and a half million deaths worldwide (as of 15 September 2022), as well as disrupted economies, closure of schools, and many other adverse effects, it is hard to think of the COVID-19 pandemic as anything but an unmitigated disaster [4]. The pandemic, however, does present a rare opportunity to observe a full-blown public health emergency response, and to identify the preparedness capacities and capabilities of EU Member States in action. The specific focus of this report is on the following issues: testing, surveillance, healthcare sector coordination, and emergency risk communication. The analysis presented in the report is also limited to the first phase of the pandemic, before the initiation of vaccination programs in December 2020.

In this context, the goal of this analysis is to capitalise on this experience to identify specific challenges that were encountered, as well as successful responses to them. The implications for measuring preparedness are also identified in order to inform outbreak preparedness efforts in the EU Member States in the future. The goal is *not* to assess or judge any specific responses by the Member States. Rather, the objective is to use the experiences of countries to identify specific preparedness capacities and capabilities that were essential in the response to COVID-19, and thus should be included in preparedness assessment tools.

The section, 'Methods' provides background on some critical issues in measuring public health emergency preparedness, including the role of assessment tools and indicators in the preparedness cycle. This section also discusses how the public health system's response to the COVID-19 pandemic presents an opportunity to refine measurement tools for preparedness, especially with regard to the areas that are the focus of this report. The section ends with a summary of the methods used to prepare the analysis.

The section, 'Results' uses the approach described in the 'Methods' section to analyse the implications of the findings for assessing PHEP preparedness in the future, particularly *what* to measure. In this section, critical aspects of testing and surveillance are identified. Healthcare sector coordination and emergency risk communication areas are discussed as well. More comprehensive analyses of these areas will be published separately.

Overarching conclusions are presented to reflect on capacities and capabilities that were essential in the response to COVID-19, and have to be further incorporated in the preparedness planning. Moreover, there is a focus on capacities and capabilities for response that are not well represented in existing preparedness measurement frameworks.

The final section on measurement approaches explores the implications of the 'Results' and offers suggestions on *how* to measure preparedness. In particular, the analysis in this report suggests that a peer-assessment approach might be useful in the EU's efforts to assess preparedness.

2 Methods

2.1 Measurement framework

Assessing preparedness is difficult because serious public health emergencies and cross-border outbreak events are relatively infrequent, providing few opportunities to assess outcomes by direct observation in after-action reviews. Moreover, each event entails unique aspects specific to its context. Therefore, statistical approaches common in other areas of healthcare (e.g. post-surgical mortality, or proportions of patients receiving an indicated preventive service) are not available. Furthermore, the range of activities that constitutes an effective public health emergency response is complex and multifaceted, so it can be difficult to even retroactively identify the best response to a specific situation, given the absence of the counterfactual (i.e. what would have happened had some other response been undertaken). An effective approach in one community may be less so in others [5].

Moreover, PHEP systems are multi-jurisdictional and multidisciplinary, and vary markedly from one EU country to another. Public health agencies are hierarchical, involving national, sub-national and local components. In cases of cross-border outbreaks, public health agencies of different countries also work in multi-national collaborations. Other entities (which also differ among countries) that support public health preparedness include key players in the health sector (e.g. hospitals, primary care physicians and emergency medical services), as well as counterparts in non-health sectors (e.g. agricultural and environmental protection agencies, civil protection agencies, educational institutions and law enforcement). Some of these entities may not think of themselves as having a role in public health. In addition, especially in large-scale events, one or more emergency operations centres (EOCs) are often activated under the control of a ministry of defence or interior (including civil protection), or directly under the Head of State. Lastly, communities and civil society play important roles, creating a complex reality with different stakeholders, powers and degrees of involvement.

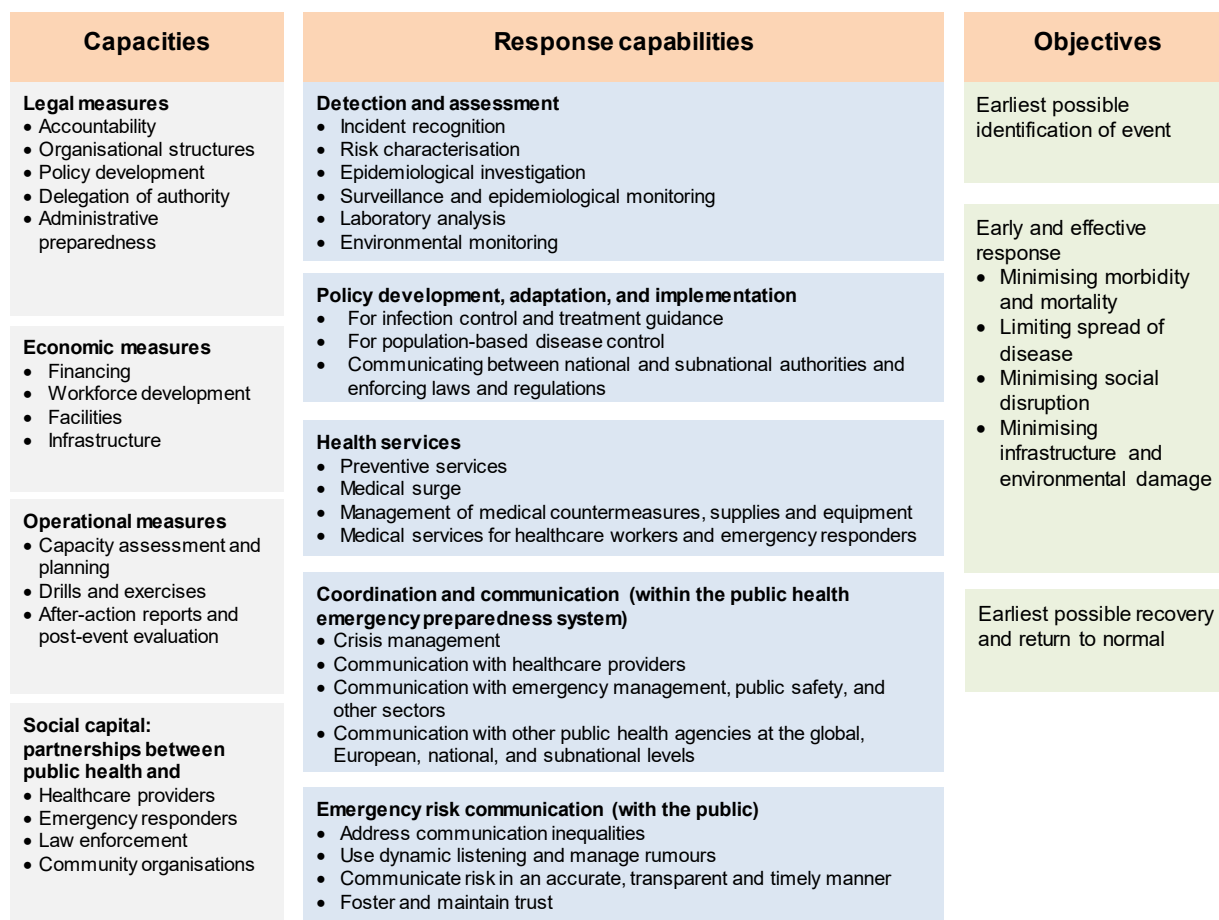
Consequently, responsibility and accountability for public health preparedness is diffuse, making it difficult to determine which partner's performance to measure, and how to hold each partnering entity accountable for its contributions [6].

Consistent with the WHO [7, 8], ECDC's preparedness cycle in seven stages is described in Figure 1 (below). Assessments can be made in two stages (stage 2 and stage 6). Firstly, at the pre-event phase, capacity building and maintenance require assessment of preparedness so national systems can identify capacities that need to be strengthened. Secondly, post-event evaluations should be framed in terms of capacities found to be deficient, so that the findings can be implemented to enhance capacities for future events.

Figure 1. Public health emergency preparedness process [9]



In order to organise the approach to these measurement challenges, a logic model was used (for the purposes of this work) to help clarify what must be measured at different stages of the preparedness and response cycle. In particular, the ECDC preparedness logic model [10] was used, which was developed on the basis of scientific evidence, experiences of public health practitioners, and analyses of public health emergencies. As illustrated in Figure 2 (below), the logic model specifies the **objectives** of public health preparedness, as well as the measurements of preparedness **capacities** and the **response capabilities** needed to achieve them.

Figure 2. ECDC logic model for public health emergency preparedness in EU Member States [10, 11]

The ECDC logic model distinguishes between measurements of preparedness **capacities** and **response capabilities** [10]. For those familiar with Donabedian's approach to healthcare quality measurement [12], capacities are somewhat comparable to structural measures, and capabilities to process assessments. The analogy is not exact, however, the following distinctions are made (Annex 1 discusses this in more details):

- **Capacities** represent the resources: infrastructure, pre-existing response mechanisms, knowledgeable and trained personnel that a public health system must draw upon. Much of *what* public health preparedness organisations do in peace time, i.e. between events – planning, training, and acquiring equipment and supplies – is intended to build capacity for emergencies in the future. For example, the capacities corresponding to the 'detection and assessment' section of response capabilities including among others: testing capacities, case definitions and protocols, electronic reporting systems for notifiable diseases connecting the local, regional and national, capacity to analyse surveillance data, characterise risks, number of trained and working epidemiologists, communication experts and other relevant professionals, and established procedures and processes to report to and consult with European and international organisations (such as, ECDC and WHO).
- **Response capabilities**, on the other hand, describe the actions which a public health system is capable of undertaking to effectively identify, characterise, and respond to emergencies, i.e. conducting surveillance and epidemiological investigations, providing diagnostic testing and vaccines, ensuring surge capacity for healthcare services, communicating risks to the public, and coordinating responses through an effective incident management system. Capabilities, therefore, are latent characteristics of PHEP systems that are best assessed in actual emergencies or other situations in which the PHEP system responds to an emergency.
- **Outcomes** are used to measure the quality of the PHEP response, and can be used to inform how the response might be improved by increasing certain capacities and capabilities. Outcomes such as morbidity and mortality can be measured during an actual event, but are not useful as preparedness indicators since they are only available after the actual event. Moreover, the logic model lays out the prospective relationship between capacities, capabilities and the objectives of a PHEP system: the earliest possible identification of an event; an early and effective response that minimises morbidity and mortality, limits the spread of disease, minimises social disruption, and minimises infrastructural and environmental damages; and enables the earliest possible recovery and return to normal. The relationships built into the logic model enable planners to determine what steps are necessary ahead of an event to achieve the best objectives.

The frequent occurrence of small-scale disease outbreaks provide an opportunity to observe PHEP systems in action, but do not test the full range of capabilities that is required in a global pandemic. Consequently, most preparedness metrics focus on capacities, which are organisational characteristics. However, capacity metrics are problematical, as there is relatively little evidence to connect measurements of preparedness **capacities to response capabilities** and **objectives** to achieve outcomes [13]. Consequently, most current preparedness metrics are based on professional judgement informed by standard public health operations and previous emergencies.

From this perspective, COVID-19 provides a rare opportunity to observe a full-blown public health emergency response. Referring to PHEP process outlined in Figure 1, post-event evaluation (stage 6) can provide opportunities to identify gaps in capacities so they can be improved for events in the future (stage 7). In a sense, the analytical process is backwards. The causality in the logic model flows from left to right, i.e. the capacities enable the capabilities, which in turn help PHEP systems meet their objectives. The analysis, on the other hand, starts on the right side by using objectives such as morbidity and mortality to identify situations in which preparedness systems seem to have been inadequate. The next step flows left, analysing which response capabilities were ineffective and what capacities – had they been in place in advance – might have made a difference.

The response of EU Member States against COVID-19 involved many public health emergency preparedness capabilities, but the first months of the pandemic particularly stressed three sets of capabilities which are the focus of this report: testing and surveillance, healthcare sector coordination, and emergency risk communication.

The pandemic provided an opportunity to not only observe how the specific capabilities in these areas functioned individually, but also how they interacted to ensure a rapid, comprehensive and sustainable response. For instance, one can observe how testing enabled accurate surveillance, and how surveillance informed risk characterisation and communication.

The gaps in capacities that were observed during the pandemic, provide a good indication of *which* capacities should be the focus of preparedness metrics in the future. For example, experiences with testing and surveillance suggest that it is not enough to measure the existence of capacities for testing and reporting common notifiable diseases, but also the flexibility to adapt these systems for a novel pathogen and to scale up capacities to meet surges in cases. Changes made to PHEP systems during the first wave of COVID-19 to address problems that emerged in real time or afterwards to prepare for the re-emergence of the virus in the autumn of 2020 or the subsequent winter can be seen as indications of preparedness capacities and capabilities that should be analysed and eventually included in measurement tools for preparedness.

Moreover, because the same pathogen affected every country both globally and in Europe, a comparative analysis can help identifying the relationship between capacities, capabilities, and objectives. In particular, such an analysis can clarify the most important elements of preparedness for response. However, comparative analyses have to take into account the differences between countries with respect to the structure of their governments and public health systems, their healthcare delivery systems, priority objectives, when and how the pathogen arrived, as well as other factors such as population composition, socio-economic factors, and political dynamics. A partial solution to this challenge is to focus on capabilities, rather than capacities. For example, every country needed to conduct testing and surveillance, but different systems and methods were used to accomplish this, depending on governmental structures, existing capacities, and activation of pandemic preparedness plans.

2.2 Project approach

To meet the goals of the project i.e. to capitalise on this experience to identify specific challenges that were encountered during the management of COVID-19, as well as successful responses to them, the research team contracted by ECDC, in collaboration with the ECDC staff undertook the following activities:

- Five EU Member States were identified and agreed to participate in the project: Croatia, Finland, Germany, Italy and Spain. These countries were chosen to illustrate different national organisational structures and responses to the pandemic. The research team's familiarity with the countries' characteristics (including language abilities) were taken into consideration, as were the countries' availability and willingness to participate.
- Based on a preliminary review of issues raised during the first wave of the pandemic in Europe, the following areas were chosen to be the focus of the project: testing, surveillance, healthcare sector coordination, and emergency risk communication. As the first two areas are highly interdependent, testing and surveillance were grouped together during the discussions and the analysis. Although the pandemic affected the five countries at different times, the analysis focuses on the first six months of 2020 and the steps taken afterwards to address gaps identified during this period. The analysis does not explore the period after the initiation of vaccination programs in December 2020.
- Based on the conduction of rapid literature reviews, as well as pandemic preparedness plans, reports, and other documents gathered from the five countries, interview guides were elaborated highlighting key issues for each of the three areas of inquiry.

- In collaboration with the ECDC National Focal Points (NFPs) for Preparedness and Response in the five countries, interviews were conducted with individuals knowledgeable about the areas of inquiry, in each country. This included discussions with the NFPs for Preparedness and Response, as well as other recommended experts in the countries. Pawson and Tilley's approach to conducting stakeholder interviews was employed [14].
- Preparedness measurement issues raised in each of the three areas were analysed separately. These were based on a) documentary analysis, b) interviews of country representatives, and c) other literature identified through the conduction of rapid literature reviews. The capabilities that countries needed during the pressure of the pandemic as well as steps that could be taken in preparation for the next public health emergency, are summarised. The three summaries conclude with an analysis of the preparedness measurement issues identified as a step towards an improved PHEP measurement framework. Preliminary results were discussed in virtual meetings with the ECDC NFPs for Preparedness and Response.
- The implications of the findings of the three substantive summaries for measuring public health emergency preparedness in EU Member States were also analysed. Comparisons were carried out (for what and how to measure) with other well-developed preparedness assessment tools: the ECDC Health Emergency Preparedness Self-assessment (HEPSA) tool [9], the WHO Joint External Evaluation (JEE) tool [8] and Global Health Security Index (GHSI) [15]. Some considerations were also made on linking assessment of public health preparedness to a quality management system (QMS).

3 Results

3.1 What to measure

This section summarises the results of three in-depth analyses of the findings regarding *which* aspects of PHEP systems should be measured in the future. It begins with some overarching conclusions about capacities and capabilities that were essential in the response in the three focus areas of the report. Capabilities that were found to be important during the pressure of the pandemic are summarised and suggestions for modifying the ECDC PHEP logic model's capabilities reflect the pandemic experience. Steps that could be taken in preparation for the next public health emergency are also identified. Indicators of whether these steps have been taken are the basis for specific measurement tools for preparedness.

It is recognised that there are many measurement frameworks (see Haeberer et al [16] for a more complete discussion). However, for the sake of concreteness, the capabilities and capacities identified in the analysis were compared primarily with two well-developed preparedness assessment tools: the ECDC HEPSA tool [9] and the WHO JEE tool [8]. To a lesser extent, the analysis also refers to the GHSI [15]. These tools address different topics and take varying approaches to measurement, therefore, providing a useful point of departure for our results.

3.1.1 Testing and surveillance

Of the six capabilities under the 'Detection and assessment' group in the ECDC PHEP logic model, two were especially stressed during the initial phase of COVID-19 in Europe: 'laboratory analysis' and 'surveillance and epidemiological monitoring'. Thus, this section addresses these two areas first, with the other four areas discussed in lesser details afterwards.

Laboratory analysis

In the ECDC PHEP logic model, the 'laboratory analysis' capability is defined as, 'The technical ability to identify (possibly novel) pathogens, monitor antimicrobial resistance, and to handle large numbers of samples submitted for diagnostic purposes'.

The primary finding in this area from the literature reviewed and discussions with public health experts in the five countries, is that being able to conduct testing at scale (a capability) was especially critical in the early phase of the pandemic in EU Member States. The inability to conduct tests in sufficient numbers and obtain rapid results had implications for clinical decision making. The COVID-19 experience showed that the inability to scale up testing operations also created problems for public health operations (e.g. epidemiological investigations, contact tracing), situational awareness (e.g. when restrictions on movement could be lifted), and risk assessment and characterisation.

For example, the Veneto region of Italy started contact tracing and case finding early and expanded these further in the course of the epidemic [17]. This required a drastic scaling up of testing capacity, targeting mildly symptomatic cases, focusing on home diagnosis and care, and tracing contacts as much as possible. According to Pisano, Sadun and Zanini [18], this proactive approach to testing helped to reduce the number of cases and deaths. On 22 January 2020, a network of 31 laboratories with diagnostic capabilities was established in Italy to perform laboratory analysis for suspected cases of SARS-CoV-2 infection according to the protocols set by WHO. At the same time, the National Institute of Health – Istituto Superiore di Sanità, ISS - (WHO National Influenza Centre - NIC/ISS) was identified as the national respiratory virus infection laboratory for confirmation and reporting to WHO of all cases of SARS-CoV-2 infection identified in Italy.

The ability of countries to scale up testing depended in part on a variety of existing capacities: the ability of universities, hospitals, and commercial laboratories to develop a test for a new pathogen, and of the government and regulatory structures to approve it; the availability of swabs, reagents, and other supplies; having trained staff or the capacity to rapidly train new staff to conduct testing at scale; and the capacity for reporting either by existing or newly established electronic reporting networks that include public and private entities.

It also depended on the flexibility and resilience of the public health system, especially regulatory agencies, to approve a new test; to identify additional sources of laboratory capacity (such as using university, hospital, commercial or veterinary laboratory capacity for SARS-CoV-2 testing); and to develop guidance regarding which tests should be used and when. For example, scientists at the Charité – Universitätsmedizin hospital in Berlin (Germany) developed and validated one of the first specific PCR tests to detect the presence of SARS-CoV-2 in patients, in January 2020. Given how quickly the test itself was developed, Germany was able to turn its attention early to scaling up testing capacity. The country was well positioned to do this because its laboratories had the expertise, accreditation and equipment to conduct PCR assays and quickly deliver diagnoses. Laboratories that normally dealt with human samples required no additional licensing, but arrangements had to be made for research and veterinary laboratories, for example, removing the requirement that medical doctors sign off on the results [19].

In Finland, as reported during the interviews, when the first case was detected in January 2020, infrastructure and regulatory structures were already in place, so PCR testing was introduced very early. In particular, PCR assays were up and running a week after publication at national respiratory virus infection laboratory at the Finnish Institute for Health and Welfare (THL) and in the largest clinical microbiology laboratory (HUSLAB) in the Hospital District of Helsinki and Uusimaa (HUS). The test was rapidly available in the other clinical microbiology laboratories at four university hospitals. Prompt collaboration regarding regulatory matters with the Finnish Medicines Agency (Fimea) facilitated the use of commercial assays as in-house tests when they became available.

As reported in the interviews, at the beginning of the pandemic, Spain had only one national respiratory virus infection laboratory that had experience with SARS-CoV-1. Early in February 2020, other laboratories developed the ability to conduct PCR testing, but could only process a small number of samples. Veterinary laboratories were available to supplement this effort, but were only used in the Aragon autonomous community and for a limited time. Initially, testing was mainly conducted by public laboratories. Private laboratories were employed only in some regions and mainly for sequencing rather than PCR testing. Non-hospital laboratories were incorporated as well, but it was challenging as IT systems were not adapted to collaborate with public laboratories.

These findings have several implications for preparedness metrics. ‘Laboratory analysis’ proved to be an important capability in the COVID-19 response. Even though the substantive content of the logic model capacity is basically correct, ‘laboratory analysis’ may not be the best label to convey the concept of operating at scale, processing a large number of samples and reporting results in a timely way. In addition, the importance of testing capabilities for a range of public health operations, including surveillance and situational awareness, risk assessment and characterisation should be made more explicit.

The HEPESA tool does not include any metrics on laboratory capacities and capabilities in either the surveillance or risk assessment domains. The domain, ‘event response management’ includes one measurement (laboratory services are available to test for priority health threats) on laboratory capacity, but does not reflect the ability to scale up this capacity for a new pathogen.

Apart from a section on biosafety and biosecurity, the JEE tool also includes a ‘National Laboratory System’ section with indicators for:

- laboratory testing for detection of priority diseases
- specimen referral and transport system
- effective modern point-of-care and laboratory-based diagnostics
- laboratory quality system.

The EU Laboratory Capability Monitoring System (EULabCap) [20], a tool which is separate from HEPESA and was last completed in 2016 and published in 2018 [21], includes 60 detailed capacity and capability indicators for primary diagnostic testing, national reference laboratories, and surveillance/epidemic response support.

None of the metrics address the system's ability to scale up during a pandemic. The complexity of sub-national laboratory networks is implicit in the JEE assessment framework (as well as EULabCap's 'National reference laboratory assessment'), but not clearly spelled out.

As scaling up under the stress of an emergency is characteristic of preparedness systems, it is difficult to measure this feature during peace time. For this purpose, the 'stress tests' mentioned in proposed EU legislation on health emergency preparedness and response [2], which are intended to assess how a system would perform in an emergency, as well as after-action reports, could provide useful information.

For example, an indicator on scaling up testing operations during a public health emergency might assign scores as follows:

- The country has no plan to scale up testing operations during a pandemic.
- The country has a plan to scale up testing operations that have never been tested.
- The country has a plan to scale up routine testing operations that have been tested in drills (which test the execution of existing plans).
- The country has a plan to scale up testing operations that have been tested in an actual public health emergency or a stress test.
- The country has a plan to scale up testing operations that have been shown to be effective in an actual public health emergency or a stress test.

Surveillance and epidemiological monitoring

In the ECDC logic model, the 'surveillance and epidemiological monitoring' capability is defined as 'Indicator- and event-based surveillance, including case reporting and active surveillance to identify outbreaks, characterise affected population groups, monitor disease trends and the impact of control strategies'.

The primary finding from literature reviews and interviews with public health experts in the five countries suggests that providing national surveillance data during the first months of the COVID-19 pandemic was challenging in two respects: modifying existing infectious disease reporting systems to add a new 'notifiable disease'; and developing or adapting surveillance systems on an ad hoc basis to address unmet surveillance needs (e.g. syndromic surveillance, hospital-based surveillance systems). For example, at the onset of the pandemic, data availability was a challenge in Italy [18], as well as many other countries.

The challenges reported above were in part due to the hierarchical structure of national public health systems. Although specific organisational structures and responsibilities varied substantially across the five countries that were part of this study, these systems typically had a national public health authority and reference laboratories, as well as sub-national authorities (e.g. 16 regions of Germany (German Länder), the Autonomous Communities of Spain, the Italian Regions), with the local administration governing or monitoring implementation of public health and healthcare services. Case reports are mainly generated by primary care physicians and hospital providers, which, in some countries are not part of the public health surveillance system and are overseen by separate agencies. As a result, making the necessary changes to the infectious disease surveillance systems required extensive communication and coordination among many entities in multiple geographical areas, at different levels of the hierarchy, including public- and private-sector entities. Changes were required to adapt to the reporting requirements. For example, Germany's federal system, has led to varied approaches and guidance for various aspects of the pandemic [22]; legislative changes were needed to change surveillance systems.

In Italy, the first country to document and report the COVID-19 outbreak in Europe, guidance to the Regions was provided by the Italian Ministry of Health (MoH) for case notifications and event-based surveillance in January 2020, based on existing knowledge. The Italian plan for COVID-19 prevention and response, describes how an integrated surveillance system was implemented at a later stage from autumn to winter, 2020 [23]. This system combined epidemiological, case-based (ISS) and aggregated (Ministry of Health) data, which were also integrated with other sources, including events detected by the project-funded National Epidemic Intelligence (EI) Network. The Italian influenza pandemic plan (2021) highlights the importance of sharing data and implementing operational protocols/tools in the inter-pandemic phase [24]. Its implementation led to the legal endorsement of the EI Network in June 2021.

Early in January 2020, the Spanish Ministry of Health and the Autonomous Communities (ACs) developed a protocol for the early detection of COVID-19 cases [25]. Initially, samples were analysed at the national reference laboratory and soon in hospitals and laboratories in the different regions as capacity developed. During the first wave, due to overwhelmed public health systems and great pressure, each autonomous community compiled the epidemiological information at the regional level, from where it was further notified to the national level. Reporting to the national level was aggregated (numerical) and the cases were assigned to the date of notification at the national level.

Despite the early start, there were challenges because the Autonomous Communities had different data systems which could not communicate their findings. However, at the beginning of May 2020, with a favourable epidemiological situation, the Committee coordinating response measures, agreed that the daily notification of cases at the national level would be exclusively individualised, after reviewing and simplifying the variables to be notified to facilitate this process. This improved the completeness of the notifications, the quality and timeliness of the analyses and therefore, the follow-up on the development of the epidemic. Some surveillance processes were automated and simplified, and the individual data of each confirmed case was entered into SiViEs (a national electronic surveillance platform). Therefore, since May 2020, case-based information was reported to the national level as the process for the regions to include the information was improved and automatised. Other information systems were developed, e.g. hospital occupancy, outbreak surveillance and laboratory surveillance.

In Croatia, as it emerged during the interviews, at the beginning of the first pandemic wave, protocols assigned hospitals the responsibility for testing and reporting positive cases to the public health institutes in their respective counties. Initially there was no national database, but one was subsequently developed and made available at the national level for surveillance purposes.

These findings have a number of implications for preparedness metrics. 'Surveillance and epidemiological monitoring' e.g. the 19 metrics in the HEP SA 'surveillance' domain (refer to Table 1) are appropriate, but incomplete because they do not address the need to adapt existing surveillance systems to a new pathogen.

The JEE framework is appropriate and more comprehensive than HEP SA. The 'surveillance' section indicators include:

- indicator and event-based surveillance systems
- interoperable, interconnected, electronic real-time reporting system
- analysis of surveillance data
- syndromic surveillance systems and
- reporting network and protocols in country (which is currently placed in the 'reporting' section in the second edition of the JEE guidance).

The literature review and the interviews also identified three important characteristics that are not well represented in either the HEP SA or the JEE tool:

- The existence of methods for monitoring and integrating data from a wide range of sources related to hospital capacity or utilisation, test positivity rates, contact tracing operations, impact of mobility restrictions or other non-pharmaceutical interventions (NPIs), vaccine uptake, and other factors.
- The importance and complexity of sub-national structures for surveillance and epidemiological investigation.
- The challenges of adapting existing and developing new surveillance systems during the pandemic.

HEP SA does not include any metrics related to the epidemiology workforce. However, the JEE and GHSI include these indicators (whether the country has at least one trained field epidemiologist per 200 000 people) and the existence of field epidemiology training programs for public health professionals and veterinarians.

Note, that none of the GHSI metrics address the flexibility and adaptability that proved to be important in the COVID-19 pandemic.

Risk characterisation

With respect to communicable diseases, the ECDC logic model defines risk characterisation as 'identifying the (possibly novel) pathogen and its epidemiologic characteristics such as reservoir and potential sources, modes of transmission, risk groups, level and duration of infectiousness, virulence (e.g. case-fatality rate), generation time, and available control strategies'.

The literature review and discussion with experts in the countries confirmed the importance of this capability. For instance, in Germany, the ability of the Robert Koch Institute (RKI) to characterise and quickly conduct epidemiological analyses and contribute to international efforts to characterise COVID-19 risks helped inform disease control policies and provided necessary information for public risk communication. RKI published risk assessments, strategy documents, response plans, and daily surveillance reports on COVID-19, as well as technical guidelines, communicating this information via national and international public health authorities. This steady flow of information has helped the government – as well as local and intermediate public health authorities, health professionals, and the public – make critical decisions during the outbreak [22].

In Vo' (a municipality in Veneto, Italy), in the early phase of the pandemic, investigations were carried out during two separate surveys on the majority of the population (85.9% and 71.5%, respectively) through nasopharyngeal swabbing, identifying a large proportion of asymptomatic individuals among the infected people [26]. This was a crucial finding that explained the spread of the SARS-CoV-2 infection, which was different from other coronaviruses such as SARS-CoV-1 and MERS-CoV.

To address the concerns identified in the initial months of the pandemic, the Italian plan for the prevention and response to COVID-19 in the autumn to winter season issued in October 2020 [23] described a monitoring system implemented by the ISS and coordinated by the Ministry of Health, for the quantitative classification of the risk and resilience of regional public health and healthcare systems. The system included regular consultation mechanisms with technical contacts within regional health systems and a national coordination committee (Cabina di regia). In order to monitor the quality and completeness of the information reported by the regions and autonomous provinces and provide them with a tool to check the quality of their data, automatic weekly reports were sent to each region and autonomous province. Missing/inconsistent data for each indicator being evaluated and possible discrepancies in the number of cases of SARS-CoV-2 infection were reported to the integrated COVID-19 surveillance coordinated by the ISS, and to the system managed by the Ministry of Health/Civil Protection.

Similarly, the Italian influenza pandemic preparedness plan published in January 2021 [24] established the Italian influenza pandemic preparedness network made up of public health representatives of the Regions and autonomous provinces as well as representatives of relevant institutions. This reference network provides for a dynamic approach to preparedness that can interface with the well-established epidemiological and virological networks for indicator-based and event-based surveillance (for example the international InFluNet network and the Italian Epidemic Intelligence (EI) Network). A multidisciplinary network of experts called DISPATCH has been established and activated to focus on epidemic intelligence, pandemic scenarios, and risk assessment and to assess the potential impact of a pandemic influenza pathogen and define the risks for the population and health services by conducting ad hoc studies. The new influenza plan also outlines the importance of research and development activity of the genetic sequencing capacity of the WHO National Influenza Centre (NIC) of the ISS on strains of new respiratory viruses.

In June 2021, the Italian Ministry of Health established the Epidemic Intelligence Network, an event-based surveillance system, to coordinate all activities aimed at the early identification of risks to public health (especially those that are unusual/unexpected), their validation, evaluation and investigation. Although specifically part of the pandemic influenza plan, it is anticipated that the Network will be used to monitor other emerging pathogens. The Network also can be activated by the Ministry of Health to monitor the evolution of international pandemic alerts by creating situation awareness reports suited to national information needs [27].

HEPSA has an entire 'risk assessment' domain, with a number of specific metrics. In addition, two metrics in the 'surveillance' domain relate to the use of data to inform relevant sectors and stakeholders. The JEE tool, on the other hand, addresses national strategic multi-hazard emergency risk assessments (risk profiles) and resource mapping in preparation for a health emergency, but says little about risk characterisation during an event beyond one indicator on the analysis of surveillance data.

However, the ECDC logic model's description of risk characterisation is incomplete. It comprises two other capabilities ('incident recognition' and 'epidemiological investigation') which are related to epidemic intelligence, and perhaps should be included in a 'risk characterisation' capability. The COVID-19 experience in the countries that participated in this project demonstrated that the surveillance systems have to be complemented by additional data on situational awareness, including epidemiological intelligence, and this knowledge has to be translated into action. This includes information about how the epidemiological situation and social impact of the pandemic varies over time and in different areas of the country.

3.1.2 Healthcare sector coordination

Dealing with a public health emergency, especially a large-scale one, requires coordination between a multiplicity of actors. Following the ECDC preparedness logic model, four key capabilities were identified which healthcare organisations need to develop in order to tackle large-scale health emergencies.

The first three capabilities are directly drawn from the logic model: a) 'management of medical countermeasures, supplies and equipment', b) 'medical surge', and c) 'hospital infection-control practices'. In addition, we propose a new capability: 'coordination of population-based medicine'. This capability captures the COVID-19 experience in EU Member States more accurately, than the current logic model's 'preventive services'. 'Population-based medicine', in the context of this report, means health services, mainly primary care services, provided in out-of-hospital settings.

The following sections discuss the critical issues that countries faced, capabilities that were necessary under the pressure of the pandemic, the steps that can be taken in advance to prepare, as well as the crucial aspects that can be the basis of preparedness indicators.

Before proceeding, a clarification is needed – the countries that participated in this project (Croatia, Finland, Germany, Italy and Spain) finance and manage health services in different ways. The five health systems analysed differ in various dimensions [28–39]: the way in which the services are financed; the public or private nature of the service providers; the level of decentralisation and the allocation of competences between the different tiers of government; the level of integration of the healthcare delivery system; the comprehensiveness of the basic package guaranteed by the compulsory insurance scheme; and the way in which prevention and public health services are organised. It is clear that the organisational characteristics of individual national health systems influenced the way each country responded to the pandemic.

However, an attempt has been made – as far as possible – to go beyond the specificities of individual national contexts, in order to identify common challenges posed by the pandemic, and problems as well as solutions, that can be generalised and extended to other contexts. Thus, although the considerations and suggestions developed in this report tend to be of a general nature, it is also certain that they will have to be applied and translated according to the organisational specificities of individual national contexts.

Management of medical countermeasures, supplies and equipment

In the ECDC logic model, this capability is defined as the ‘ability to procure, distribute and manage countermeasures, supplies and equipment, including personal protective equipment (PPE), during an incident’.

The COVID-19 experience has shown the challenges of distributing existing stocks of medicinal supplies and equipment promptly and widely to people who need them. This required early identification of what equipment is needed and what is in short supply, which channels and modes of supply are most effective, and in some cases, setting priorities for limited stocks.

The COVID-19 experience also identified challenges in procurement. Stocks cannot be unlimited; rather they are intended to cope with the ‘first impact’ of a public health threat, after which additional supplies are needed. However, the demand of stocks depend on the type of health emergency, and it is difficult to predict in advance which products should be stocked, and at what level (national, sub-national, local) the contingency stocks are maintained. The COVID-19 experience also identified challenges in procurement in a large-scale crisis, because of high demands occurring simultaneously in many countries and the respective shortages of certain products in international markets. This led countries to explore the use of joint procurement which can take place at different levels: international, national, regional or local, including processes that might deviate from standard procurement protocols. At the EU-level (see Decision No. 1082/2013/EU) a legal framework has been established for use by EU/EEA countries in case of a serious cross-border health threat [1]. Finland, contrary to what has been observed in other countries that struggled to maintain a steady supply of PPE, never ran out of PPE because of a stockpile gathered during the Cold War era. This helped the country to be prepared for the increasing demand for medical supplies, and was a crucial element in the country’s response to COVID-19 [40].

In Spain, as a response to a particular shortage of face masks, the central government required companies producing relevant equipment to provide information on their stocks [41].

In Croatia, the government launched national campaigns to strengthen the production of local medical goods. At the international level, it entered a bilateral agreement with China to procure more protective equipment and other medical supplies [42].

In Italy, by 8 March 2020, resources were allocated for additional medical devices and equipment [43]. The first was investing resources for protective equipment, oxygen and assisted ventilation systems [44]. One week later, Italy adopted national measures to promote and sustain the production and supply of medical devices and personal protective equipment, through the provision of non-repayable contributions to the manufacturing companies [45].

Therefore, the COVID-19 experience suggests four steps that countries might take in advance, and which could be the subject of preparedness indicators:

- Stockpile products, equipment and drugs considered essential to deal with a public health emergency.
- Maintain multiple storage sites distributed throughout the country’s territory.
- Identify the entities responsible for procurement in emergency conditions.
- Keep several purchasing channels open for redundancies.

Medical surge

In the ECDC logic model, this capability is defined as ‘the ability to provide adequate medical evaluation and care during events that exceed the limits of the normal medical infrastructure of an affected area during an outbreak of an infectious disease of high impact (IDHI) or other public health incident.’

The COVID-19 pandemic presented a number of challenges in this regard. In the face of a medical surge, the hospitals run a risk of not having enough beds and trained personnel or space to admit and treat all patients. In the case of a pandemic, staff can become infected and as experienced during Covid-19 enough specialised staff were not available. There was a shortage of machines, devices and medications to treat all patients simultaneously. Especially in an outbreak caused by a new pathogen, it was difficult to predict when the peak will arrive, how long

it will last, and which hospital departments would be most affected. Furthermore, especially if the surge is prolonged, the accumulated stress on one department may negatively affect other hospital units, even those not directly involved. Finally, health professionals may not be trained, qualified, or licensed to fulfil the new tasks assigned under stress.

According to Thompson [46], organisations can employ four strategies – either individually, or in combination – to manage peak demand: buffering, smoothing, forecasting and rationing. Buffering means setting aside resources in excess of normal requirements that can be activated under conditions of emergency. In the case of a pandemic, smoothing can be achieved through a filtering on the basis of ‘population-based medicine’, so as to reduce the number of patients going to hospital who could be treated more adequately at home or in outpatient community facilities. This can reduce the pressure on hospital facilities, and spread the demand over a longer period. The third strategy, forecasting, is the ability to foresee the epidemiological curve. In the case of epidemics, such forecasting (which allows hospitals to reorganise, schedule staff shifts, stockpile, etc.) can be facilitated by the use of mathematical and statistical models. The last strategy is rationing, which is usually implemented when the previous ones have failed. Since it is not possible to simultaneously take care of all the patients who need care, it is necessary to decide who to treat first and who later. During COVID-19, individual countries applied these four strategies at different stages of the pandemic, in different ways, often combining them.

Healthcare facilities must also be able to scale up depending on circumstances, i.e. quickly decide which measures are the most effective; transfer healthcare staff from one unit to another; transfer patients from one facility to another; suspend non-urgent activities; recruit new staff; create ad hoc facilities; coordinate with outpatient care settings whenever possible, to get support and distribute the burden and so on.

From March 2020, hospitals in northern Italy reported system saturation, due to the high level of patient loads requiring intensive care. The shortage of hospital beds and ventilators as well as shortages of personnel at all levels represented a concrete threat leading to the system’s collapse. In order to support the care of COVID-19 patients, health staff were transferred from other services and disciplines. Moreover, civil medical volunteers and other healthcare workers started to operate in the most affected regions [47] (this information was shared during the interviews). At the beginning of March 2020, exceptional measures were planned, including the recruitment of healthcare personnel, such as residents, nurses and general practitioners (GPs). Retired healthcare workers were also recalled to service [44].

The persistent modernisation of the German healthcare system over the last 20 years led to more hospital beds, more ventilators, more intensive care unit beds and more hospital doctors per capita compared to any other country in Europe [48–50]. However, having a high number of intensive care beds was not sufficient to meet the needs and utilise the whole capacity because of shortages of nurses. Moreover, intensive care units could not respond to non-COVID-19 patients, because staff qualified to tend to severely ill patients were pooled together within hospitals.

At the beginning of the pandemic, health facilities in the worst-affected regions of Spain struggled because of inadequate intensive care capacities and insufficient number of ventilators. Subsequently, a decree allowed the regions to take over the management of private health services and military installations were used for public health purposes [41]. The decree also allowed the hiring of graduates without specialisation, e.g. final-year medical and nursing students, and extending contracts of medical residents to address the shortages of health staff.

Therefore, the COVID-19 experience suggests five steps that countries might take in advance, and which could be the subject of preparedness indicators:

- Develop a healthcare system emergency plan.
- Design hospital organisations to be flexible and scalable. If one organisational component is under pressure or out of order, another must be able to replace it.
- Design hospital facilities with redundancy [51]. This means building emergency reserves (buffers) in advance, i.e. more beds, staff and equipment than strictly necessary under normal conditions.
- Train multi-purpose health personnel who can be used for different tasks according to need (task shifting).
- Prepare a plan on how to return to normality, i.e. recovering burned out staff and clearing the backlog caused by the application of rationing strategies (delayed non-urgent treatments).

Hospital infection-control practices

In a pandemic, healthcare settings and health personnel can become disseminators of contagion. A capability referring to infection control is mentioned in the ECDC logic model, but there is no specific rubric on hospital infection control practices. In particular, the COVID-19 experience has shown that, under the pressure of a public health emergency, healthcare organisations must be able to: decide promptly when to activate previously developed protocols; identify facilities (or parts of facilities) dedicated exclusively to the care of infectious individuals; and depending on the circumstances, decide to treat patients in their own homes as much as possible, including using available telemedicine tools.

For example, in Italy, early in the pandemic, ISS set up a working group specifically dedicated to infection prevention and control (IPC), which among other activities was also responsible for the publication of a series of technical reports aimed at providing guidance on IPC [52–54].

Therefore, the COVID-19 experience suggests two steps that countries might take in advance, and which could be the subject of preparedness indicators:

- Draw up infection-control protocols for hospital healthcare facilities containing precautions to be observed by staff, patients and visitors, and have all the necessary equipment available to implement the plan.
- Develop a plan for each hospital facility to separate the flow of infectious patients (and suspected cases) from non-infectious patients.

Coordination of preventive, primary care and other outpatient services

The ECDC logic model includes a 'preventive services' capability, that focuses on providing vaccines and other prophylactic measures, but the COVID-19 experience demonstrated that this was not sufficient to describe the challenges in a pandemic. Thus, it is suggested to add a capability to address the 'coordination of preventive, primary care and other outpatient services'. This is defined as 'the ability to activate and strengthen – during an outbreak of a high-impact infectious disease – public health and primary care services, coordinating all providers (including public and private as well as social and mental health support agencies) using integrated pathways between out and inpatient care'.

The COVID-19 experience shows the importance of coordinating patient care between out- and in-patient settings, both in the interest of the patients and to help avoid overcrowding the hospitals. This is complicated, however, because in many countries, public health, primary care providers and hospitals do not belong to the same organisation. Thus, they cannot be coordinated hierarchically. Moreover, healthcare providers, especially those practising outside the hospital are difficult to coordinate because they are distributed throughout the country's territory and have diverse ownerships (public/private).

Coordinating mechanisms demand that systems have certain capabilities to perform under the pressure of a health emergency. In a pandemic scenario, the population-based healthcare professionals should be trained to make flexible and quick decisions to identify the most effective solutions for treating patients, including providing care at home, using telemedicine solutions, and ensuring that integrated and multidisciplinary teams are involved for healthcare provision when necessary.

Finally, communication between healthcare professionals (out- and in-patient, and the other nodes of the emergency network) must be two-way. On one hand, the population-based professionals must be constantly kept informed and updated on the overall epidemiological situation and possible medical surge capabilities at different levels of healthcare provision. On the other hand, outpatient services must quickly transmit the information they collect to hospitals and other emergency responders for timely and informed decision making.

In Italy, the response to the COVID-19 pandemic in various regions was diverse due to the different organisations of regional healthcare systems. Indeed, some regions have a higher density of hospitals, while others have more developed territorial/population-based services. Difficulties of GPs in communicating with other services and lack of coordination among the services were reported as major challenges [55, 56]. During the first wave of the pandemic, the Italian government approved the introduction of the USCA (Special Care Continuity Units) to offer specialised treatment at home for COVID-19 patients without severe symptoms to prevent hospital admissions at a later critical stage [44, 47]. In addition, the Italian Ministry of Health announced the recruitment of community nurses and social workers to provide integrated care in the respective territories.

In Finland, as emerged from the interviews, a web-based national Omaolo COVID-19 symptom self-assessment toolⁱⁱ was launched in March 2020. The tool enabled primary care to effectively assess a large number of potential cases, and relieved pressure from telephone and in-person services. As testing capacity increased, direct test-booking was linked to Omaolo for people with mild symptoms. In the City of Helsinki, which was the hardest hit municipality in Finland in the early phase of the pandemic, this enabled both large-scale active case-finding for contact-tracing as well as the management of patient-inflow to specialised COVID-19 out-patient clinics in primary care, or to hospital emergency departments in tertiary care. The Hospital District of Helsinki and Uusimaa (HUS) is

ⁱⁱ More information on the Omaolo tool can be found here:

Vesa Jormanainen, Risto Kaikkonen, Sanna Isosomppi, Jari Numminen, Ilkka Kunnamo, Tommi Salaspuro, Hanna Nordlund. *Suomalaiset löysivät koronavirustaudin oirearvion verkkopalvelun nopeasti: koronavirustaudin oirearvion vastanneet 16.3.–15.5.2020*. [The Finns quickly found the coronavirus symptom assessment online service: those who responded to the Omaolo coronavirus symptom assessment from 16 March to 15 May, 2020]. Finnish Institute for Health and Welfare (THL). Discussion Paper 27/2020. 30 pages. Helsinki, Finland 2020.

Jormanainen, V & Soininen, L 2021, Use and users of the web-based Omaolo Covid-19 symptom self-assessment tool in Finland since March 16, 2020. in *Public Health and Informatics: Proceedings of MIE 2021*. IOS PRESS, pp. 739–743. <https://doi.org/10.3233/SHTI210270>

owned by the municipalities and provides tertiary-level care. HUS and the municipalities formed a coordination group for in-patient care. Capacity data was also shared via emails.

Large-scale contact tracing was performed by the municipalities. The City of Helsinki initiated the development of a digital database for contact-tracing data (SAI COVID-19) and began to use it in April 2020. SAI COVID-19 was deployed in many other hospital districts in Finland. HUS developed a similar system (HAAVI) in September 2020 for the other municipalities in the HUS District. The two systems were later integrated for the timely exchange of data for contact-tracing between the HUS municipalities.

Therefore, the COVID-19 experience suggests five steps that countries might take in advance, and which could be the subject of preparedness indicators:

- Prepare emergency plans that identify tasks, responsibilities and procedures to be implemented in a health emergency, with particular focus on protocols and telemedicine tools to treat patients at home.
- Health personnel working at the community level must have all the tools necessary to implement these emergency plans. In addition, they must have their own stock of PPE. Coordination at sub-national/local levels by public health authorities is needed to achieve this goal.
- Train outpatient healthcare professionals to coordinate and communicate with each other.
- Identify and operationalise channels and tools to facilitate communication between healthcare professionals (both in- and out-patient) and other emergency responders. These should mainly be computer-based for timely and effective internal communication.

The issues of healthcare coordination identified during the COVID-19 pandemic are not well represented in existing preparedness measurement frameworks.

The HEPSA tool has only two indicators:

- Procedures to coordinate all relevant partners of the health system are established e.g. public health, medical and mental/behavioural health services.
- Coordination involves population-based care and resource mobilisation.

The JEE tool also has two indicators:

- System in place for activating and coordinating medical countermeasures during a public health emergency.
- System in place for activating and coordinating health personnel during a public health emergency.

The issues identified during the COVID-19 pandemic regarding healthcare sector coordination would require a revision of assessment frameworks and introduction of more comprehensive indicators to address pandemic preparedness planning.

3.1.3 Emergency risk communication

Responding to large-scale emergencies requires timely and continuous communication both with the public, and across the various organisations which are part of the public health system. Emergency risk communication (ERC) is defined as 'the real-time exchange of information, advice, and opinions between experts and/or officials, and people who face a threat to their survival, health, economic or social well-being' [57]. This section addresses preparedness measurement issues related to this capability.

The ECDC logic model includes four ERC (with the public) capabilities: a) 'address communication inequalities', b) 'use dynamic listening and manage rumours', c) 'communicate risk in an accurate, transparent, and timely manner', and d) 'foster and maintain trust'. Note that this group of capabilities is different from a separate set of capabilities related to 'coordination and communication (within the public health emergency preparedness system)', which is not covered in this analysis.

The primary finding from our analysis is that all four capabilities were challenged during the pandemic. Additionally, all countries experienced difficulties in managing an unprecedented epidemic of information. To include this important aspect, the capabilities listed in the original ECDC model are revised and expanded into five capabilities: a) 'communicate risk in a timely and transparent manner', b) 'foster and maintain trust with the media and the public', c) 'communicate risk in a clear, consistent, and empathetic manner', d) 'identify and address communication inequalities', and e) 'manage the infodemic'. The definition of 'infodemic' suggested by Tangcharoensathien et al. was adopted to describe this important fifth capability: the management of 'an overabundance of information – some accurate and some not – that occurs during an epidemic' [57].

Communicate risk in a timely and transparent manner

Based on a review of the scientific literature and the interviews conducted for this analysis, the COVID-19 experience confirmed what was known from previous emergencies: timeliness is of the essence in preparedness, and transparency in the responses of the agencies in charge is important to build trust. A lack of timeliness can negatively affect the population's perception of transparency in the work done by public health institutes and the

government, and thereby compromise the overall effectiveness of the response. This potentially reduces the public's trust in institutions, and as such, negatively impacts the government's ability to manage the crisis.

To achieve timeliness and transparency, the experts interviewed said that risk-communicators need to be included in preparedness and response efforts as part of multidisciplinary teams, and adequate resources need to be allocated to this important capability. To foster transparency, several governments created dashboards of open data and adopted an open approach to the sharing of information. This approach turned out to be nationally beneficial as well as from an international point of view because epidemiological data made available by one country were used for planning purposes by other countries preparing for similar epidemiological situations.

In addition, effective ERC was described by the interviewees as a collaborative effort within government agencies, as well as with external partners such as media and social media companies. Building these relationships and collaborations prior to an emergency is an important effort that should be included in preparedness measurement efforts.

In Spain, during the first phase of the pandemic, to enhance government transparency with the media, procedures were changed in the way journalists could ask questions at press conferences. Spain adopted the 'one spokesperson' model at the start of the crisis. However, with the progression of the emergency, a variety of experts were interviewed by the media in order to get different perspectives, which led to a multitude of messages. This posed a challenge to the government's attempt to have a cohesive voice. In Finland, to ensure transparency with the media, the government created a dedicated phone line for journalists to ask questions and an open-access database with daily situation reports. A similar approach was cited as valuable by experts from other countries.

The Italian Ministry of Health immediately set up a thematic site dedicated to the new coronavirus on the institutional portal, whose pages are updated as evidence becomes available. The pages contain information dedicated to citizens and health professionals, travellers, workers and businesses. The citizen-response service operated 24 hours a day, every day,ⁱⁱⁱ with specially trained operators and healthcare executives. Professionals involved in the response follow continuous training courses to ensure the quality of the service.

Foster and maintain trust with the media and the public

The COVID-19 pandemic has been unprecedented for the duration of public health measures and restrictions put in place. For long-term events, such as a pandemic, maintaining the attention and trust of the public on an issue over time is challenging. As Schuster et al. [58] noted in Germany, public interest in COVID-19 drastically decreased overtime within the first wave. Thus, keeping people informed about the newest developments and aware of the ongoing risk of infection was expected to be a major communication challenge, especially in the later course of the pandemic.

In addition, as pointed out by Moreno et al. [59], criticism of public authorities and trust in the sources of information became more critical as the crisis evolved. Distrust of government institutions, misconceptions regarding prevalence of the disease and feelings of vulnerability – specifically related to a lack of protection or prevention – have ultimately led to a perceived loss of personal sovereignty and free will. Consequently, individuals have turned to unproven or exaggerated sources of information and sometimes used irrational decision-making processes to regain a sense of control over their own actions and environments. This has resulted in a polarisation of society with potential impact on domestic and international security.

To foster and maintain trust there should be timely communication about knowns and unknowns, provided by a designated spoke person. The communicator (one or a team) have to acknowledge what is unknown and provide updates as soon as available and notification that decisions might change upon arrival of new evidence.

Communicate risk in a clear, consistent, and empathetic manner

This analysis highlights the fact that communication should not only be timely but as synchronous as possible across the various communication channels. To ensure a synchronous approach to communication, channels and procedures to share information with the public should be put in place prior to the emergency, including coordination between national and sub-national agencies.

This analysis also highlights the importance of identifying expert intermediaries who are knowledgeable in the technical lexicon used by the target audience (i.e. trade organisations, industries, commercial entities, etc). Mechanisms to answer questions from the public and the media were created by most governments and should be included in preparedness measurement efforts. In addition, it is important to identify individuals who are knowledgeable about cultural differences in the population and can advise on the use of empathic and culturally appropriate language that acknowledges the perspectives and feelings of the audience at whom the message is directed.

Identify and address communication inequalities

ⁱⁱⁱ A national information line was activated by the Italian Ministry of Health on 27 January 2020, where citizens could call the toll-free number- '1500' - to get answers to their questions about the new coronavirus.

Communication inequalities are fairly common. These consist of differences in how various segments of the population have access to, process and act upon the information received during a crisis. To overcome such inequalities, a multitude of channels of communication need to be used and messages need to be developed based on the literacy level and considering socio-cultural backgrounds of the target audience. In addition, the interviewees highlighted the importance of developing educational opportunities at the citizen and media-levels, with outreach and community-based efforts such as science fairs and other platforms where a scientific culture is promoted to the public. These actions should be taken into consideration when measuring preparedness efforts.

Manage the infodemic

All the four capabilities described above are related to 'infodemic management' which this analysis describes as the management of 'an overabundance of information – some accurate and some not – that occurs during an epidemic'. The management of infodemic and information disorder, starts with the ability to conduct social-listening activities to understand the public's concerns and their reactions to being exposed to the overabundance of information, mis/disinformation and the potential impact of such exposure on their behaviours. The need to monitor the spread of information across media and social media platforms and to generate mechanisms (i.e. the use of chatbots) to enhance the government's capacity to respond to questions from the public were highlighted by the national experts during the interviews. However, interviewees also stressed the importance of discerning which rumours might have an impact on behaviour, and which may not be worth the development of counter-messaging strategies. A strategic plan to conduct infodemic management is an essential component of preparedness activities, and as such, should be included in measurement efforts.

In regard to existing measurement frameworks and their inclusion of ERC measures, the HEP SA risk communication indicators include:

- A comprehensive communication strategy is developed to engage with all relevant stakeholders such as public health professionals, media and public, non-health sectors, etc.
- Communication policies and procedures to develop, coordinate, and disseminate information related to an event of public health concern are established.
- During an event, consistent messages are disseminated by a trusted authority.
- Information related to an event is disseminated to the public, in order to explain the outbreak, to establish confidence and to minimise the risk of infection.
- Risk assessments are used to aid preparedness planning and response activities.

The JEE risk communication indicators include the following items:

- Formal government risk communications plans, arrangements and systems in place.
- Existence of risk communication coordination platform and mechanisms for internal and partner communication.
- Evidence that public communication unit or team operates efficiently and effectively.
- Evidence that risk communication units systematically engage populations at community level during emergencies.
- Existence of a system to gather information on perceptions, risky behaviours and misinformation to analyse public concerns and fears.

The HEP SA and JEE tools have some limitations to be addressed. For example, the HEP SA tool acknowledges the need for trust in risk communication, whereas the JEE tool does not include trust in their measurement indicators. JEE highlights the need to meet populations at the community-level, while HEP SA does not discuss the role of communities or various sections of the population who are the target of communication strategies. HEP SA and JEE do not focus on the three specific areas that are identified in this report as critical: communication inequalities, infodemic management (which goes beyond the identification of misinformation), and transparency in communication.

3.2 How to measure preparedness

Beyond the issue of *which* preparedness capacities and capabilities they include, HEP SA, JEE and GH SI differ in format and process, i.e. *how* to measure preparedness. Based on the findings from the literature review and interviews with experts in the five countries part of the project, a suggestion would be to consider developing a peer-assessment process for assessing preparedness in the EU Member States. This would be similar in the approach to measurement and format that the JEE tool [8] adopts. But the process will cover the issues identified in this analysis, as well as the concerns identified at global, EU and Member States levels to implement the lessons learned during the pandemic. The emergency preparedness and response framework and tools by WHO such as, State Party self-assessment Annual Reporting (SPAR) [60], JEE, etc., have been revised or are currently undergoing revision. Therefore, suggestions related to the revised versions of these tools are beyond the scope of this report.

The analysis presented in this report suggests that the type of measurement approach and format utilised in the content and assessment process of the JEE tool might be useful in the EU's preparedness assessment efforts. For

the sake of concreteness, the metrics that deal with testing and surveillance are used to illustrate a comparison of the measurement formats used by JEE, HEPESA and GHSI. An in-depth discussion addresses the process through which values are assigned to these indicators.

As illustrated in Table 1 (on page 18), the HEPESA tool includes several indicators in the 'surveillance' domain, and none directly addressing laboratory capacity. Each indicator is scored 0%, 20%, 40%, 60%, 80%, or 100% using a rubric based on frequency and/or achievement, and the results are averaged. This appears objective, however, for many indicators the scoring is arbitrary. Furthermore, the results are self-reported by public health experts with no external review and validation.

The JEE tool, on the other hand, has fewer indicators but covers more aspects of testing and surveillance. The target is to strengthened indicator-based and event-based surveillance systems that are able to detect events of significance for public health and health security by incorporating epidemiological, clinical, laboratory, environmental testing, product safety and quality, and bioinformatics data; and advancement in fulfilling the core capacity requirements for surveillance in accordance with the IHR and OIE guidelines. It includes several indicators addressing testing, surveillance and related issues. Each of these is scored on a 5-point scale, with a specific rubric.

Table 2 (on page 20) displays the rubrics for another set of 'real-time surveillance' indicators. For summarising and cross-national comparisons, a score of 1 is represented as red, 2 and 3 as yellow, and 4 and 5 as green. In addition to the summary scores, a detailed qualitative report is presented, indicating not only why each score was awarded, but also providing guidance on what changes are needed to improve it.

The GHSI is similar to the JEE tool in coverage. Table 3 (on page 21) provides sample GHSI measures for Category 2 (early detection and reporting for epidemics of potential international concern). An important distinction between this and the other measurement tools is that the scores are entirely generated by an external group – the Economist Intelligence Unit (EIU). Many of the scores are taken from a country's publicly available JEE results. Otherwise, scores are based on the judgement of national experts who are presumably unbiased, but who have no public health preparedness expertise.

Table 1. Sample HEPESA 'surveillance' indicators

Surveillance performance indicators	
1	An indicator-based surveillance system is in place.
1.1	These indicators are defined in protocols to enable timely follow-up.
2	An epidemic intelligence system is in place.
2.1	Events of Public Health concern are defined in protocols, to enable timely follow-up.
2.3	The surveillance system provides real-time reporting of surveillance data.
2.4	The surveillance system is sensitive and flexible, to detect initial cases or events.
2.5	The surveillance system obtains information from a broad range of different and reliable resources.
2.6	The surveillance network includes information from veterinary surveillance systems.
2.7	The surveillance network includes information from entomological surveillance systems.
2.8	The surveillance network includes information from environmental surveillance systems.
2.9	The surveillance network includes information from meteorological surveillance systems.
2.10	The surveillance network includes information from microbiological surveillance systems.
3	The surveillance system generates an early warning signal of a possible event of Public Health concern.
4	Participation in EU surveillance networks is established.
5	The surveillance system meets EU and WHO standards with regard to epidemiological data on all diseases under EU surveillance, their case definitions, and reporting protocols.
6	Surveillance data are systematically and regularly reported to the relevant sectors and stakeholders.
6.1	All relevant surveillance systems are integrated in a network that consistently exchanges information.
6.2	Reporting networks and protocols are in place.
6.3	The surveillance system is able to provide the information necessary to inform and advice response.

Note: Each indicator is scored 0%, 20%, 40%, 60%, 80%, or 100% according to the scale below. HEPESA has a separate section for 'risk assessment', but no section for 'laboratory'.

Score	Frequency scale	Achievement scale
No (0%)	Never	Not achieved, no progress, no sign of forward action.
20%	Infrequent	Minor progress, with few signs of forward action in plans or policy.
40%	Sometimes	Some progress, but without systematic policy and/or organisational commitment.

Score	Frequency scale	Achievement scale
60%	Often	Organisational commitment attained or considerable progress made, but achievements do not meet all needs and requirements.
80%	Mostly	Substantial achievements but with some recognised limitations in capacities, capabilities and/or resources.
Yes (100%)	Always	Comprehensive achievements with sustained commitment and capacities at all levels.

Table 2. Sample JEE indicators for 'real-time surveillance' (D.2) and 'reporting' (D.3) sections

Score	Indicators: Real-time surveillance					
	D.2.1 Surveillance systems	D.2.2 Interoperable, interconnected, electronic real-time reporting system	D.2.3 Analysis of surveillance data	D.2.4 Syndromic surveillance systems	D.3.1 System for efficient reporting to WHO, FAO and OIE	D.3.2 Reporting network and protocols in country
No capacity (Score: 1)	No indicator or event-based surveillance systems exist.	No interoperable, interconnected, electronic real-time reporting system exists.	No reports related to data collection.	No syndromic surveillance systems exist.	National IHR focal points, OIE delegates and/or WAHIS national focal points have not been identified; and/or the identified focal points/delegates do not have access to learning packages and best practices as recommended by WHO, OIE and FAO.	The country does not have protocols or processes for reporting to WHO, OIE or FAO; does not have plans to establish protocols for reporting within the next year.
Limited capacity (Score: 2)	Indicator and event-based surveillance system(s) planned to begin within a year.	The country is developing an interoperable, interconnected, electronic real-time reporting system, for either public health or veterinary surveillance systems.	Sporadic reports related to data collection with notification delays.	Syndromic surveillance system(s) planned to begin within the next year; policy/legislation is in place to allow for syndromic surveillance.	The country has identified National IHR focal points, OIE delegates and WAHIS national focal points; focal points are linked to learning packages and best practices as provided by WHO, OIE and FAO.	The country is in the process of developing and establishing protocols, processes, regulations, and/or legislation governing reporting, to start implementation within a year.
Developed capacity (Score: 3)	Indicator or event-based surveillance system(s) in place to detect public health threats.	The country has in place an interoperable, interconnected, electronic reporting system, for either public health or veterinary surveillance systems. The system is not yet able to share data in real-time.	Regular reporting of data with some delay; ad hoc teams put in place to analyse data.	Syndromic surveillance system(s) in place to detect one or two core syndromes indicative of public health emergencies.	The country has demonstrated the ability to identify a potential public health emergency of international concern (PHEIC) and file a report to WHO based on an exercise or real event, and similarly to the OIE for relevant zoonotic diseases.	The country has established protocols, processes, regulations, and/or legislation governing reporting, as well as processes for multisectoral coordination in response to a potential PHEIC to WHO, and relevant zoonotic diseases to the OIE.

Score	Indicators: Real-time surveillance					
<p>Demonstrated capacity (Score: 4)</p>	<p>Indicator and event-based surveillance system(s) in place to detect public health threats.</p>	<p>The country has in place an interoperable, interconnected, electronic real-time reporting system, for public health and/or veterinary surveillance systems. The system is not yet fully sustained by the host government.</p>	<p>Attributed functions to experts for analysing, assessing and reporting data on an annual or monthly basis.</p>	<p>Syndromic surveillance system(s) in place to detect three or more core syndromes indicative of public health emergencies.</p>	<p>The country has demonstrated the ability to identify a potential PHEIC and file a report to WHO within 24 hours, and similarly to the OIE for relevant zoonotic diseases, based on an exercise or a real event.</p>	<p>The country has demonstrated timely reporting of a potential PHEIC to WHO and to the OIE for relevant zoonotic diseases. The reporting is in alignment with national and international standards at selected intermediate levels (districts or regions), based on an exercise or a real event.</p>
<p>Sustainable capacity (Score: 5)</p>	<p>In addition to surveillance systems, the country has used expertise to support other countries in developing surveillance systems and providing well-standardised data to WHO and OIE for the past five years without significant external support.</p>	<p>The country has in place an interoperable, interconnected, electronic real-time reporting system, including both the public health and veterinary surveillance systems which are sustained by the government and capable of sharing data with relevant stakeholders according to the country's policies and international obligations.</p>	<p>Systematic reporting; dedicated team in place for data analysis, risk assessment and reporting.</p>	<p>In addition to syndromic surveillance systems in the country, it has used expertise to support other countries in developing syndromic surveillance systems.</p>	<p>The country has demonstrated the ability to identify a potential PHEIC and file a report within 24 hours, and similarly to the OIE for relevant zoonotic diseases. It has a multisectoral process in place for assessing potential events for reporting.</p>	<p>The country has demonstrated timely reporting of a potential PHEIC to WHO from district to national and international levels, and to the OIE for relevant zoonotic diseases (based on an exercise or real event); the country has a sustainable process for maintaining and improving reporting and communication capabilities and its communication mechanisms are backed by established documentation (e.g. protocols, regulations, legislation).</p>

Table 3. Sample Global Health Security Index (GHSI) indicators**Category 2: Early detection and reporting for epidemics of potential international concern**

2.1 Laboratory systems <ul style="list-style-type: none"> Laboratory capacity for detecting priority diseases <ul style="list-style-type: none"> Does the national laboratory system have the capacity to conduct diagnostic tests for at least 5 of the 10 WHO-defined core tests? Is there a national procurement protocol in place which can be utilised by the ministries of health and agriculture for the acquisition of laboratory needs (such as equipment, reagents, and media)? Specimen referral and transport system <ul style="list-style-type: none"> Does the country participate in a regional or international laboratory network? Is there a nationwide specimen transport system? Laboratory quality systems
2.2 Real-time surveillance and reporting <ul style="list-style-type: none"> Indicator and event-based surveillance and reporting systems Interoperable, interconnected, electronic real-time reporting systems Transparency of surveillance data Ethical considerations during surveillance Coverage and use of electronic health records
2.3 Epidemiology workforce <ul style="list-style-type: none"> Applied epidemiology training program, such as the field epidemiology training program, for public health professionals and veterinarians (e.g. Field Epidemiology Training Program and Field Epidemiology Training Program for Veterinarians) Epidemiology workforce capacity <ul style="list-style-type: none"> Is there public evidence that the country has at least one trained field epidemiologist per 200 000 people?
2.4 Data integration between human, animal, and environmental health sectors <ul style="list-style-type: none"> Data integration between human, animal, and environmental health sectors

3.2.1 Assigning values to scales

The JEE is scored through a process that begins with an analysis and a preliminary scoring of each indicator by national experts. This is usually followed by a five-day meeting in which peers from other countries review documentation from the internal analysis, and meet with national experts to achieve consensus about scoring.

Gupta et al. [61] have evaluated the JEE process and found that strong correlations between the performance and metrics of both health outcomes and health systems suggest that the JEE tool is likely accurately measuring the strength of IHR-specific, public health capabilities. In terms of accountability, the involvement of external peers helps to increase objectivity and the relatively simple scoring system allows for international comparisons. The qualitative report, on the other hand, provides useful guidance on how countries could improve. The evaluation process could include an analysis of the performance of existing systems (as in the current JEE process) during the COVID-19 pandemic, and the 'stress tests' mentioned in proposed EU legislation on serious cross-border threats to health [2].

However, to be useful in the European context, based on the findings of this project, the authors suggest that measuring preparedness in a new tool should be expanded to include the issues identified and presented in this report. For example, in the area of testing and surveillance, the existing rubrics should be revised, or additional indicators added, to reflect:

- the challenge of scaling up testing and surveillance operations during a pandemic
- the coordination of surveillance efforts of multiple public health agencies and other entities at national, sub-national and local levels within each country.

As a starting point for discussion, Table 4 suggests a rating scale for measuring these capabilities.

Table 4. Proposed JEE-like scoring system for two new indicators

Score	Sample indicator 1: Scaling up testing operations during a public health emergency	Sample indicator 2: Coordinating surveillance efforts at the national, sub-national, and local levels during a public health emergency
No capacity (Score: 1)	The country has no plan to scale up testing operations during a pandemic.	The country has no plan for coordinating surveillance efforts during a public health emergency.
Limited capacity (Score: 2)	The country has a plan to scale up testing operations that has never been tested.	The country has a plan for coordinating surveillance efforts during a public health emergency that has never been tested.
Developed capacity (Score: 3)	The country has a plan to scale up routine testing operations that has been tested in drills.	The country has a plan for coordinating routine surveillance efforts that has been tested in drills.
Demonstrated capacity (Score: 4)	The country has a plan to scale up testing operations that has been tested in an actual public health emergency or a stress test.	The country has a plan for coordinating surveillance efforts during a public health emergency that has been tested in an actual public health emergency or a stress test.
Sustainable capacity (Score: 5)	The country has a plan to scale up testing operations that has been shown to be effective in an actual public health emergency or a stress test.	The country has a plan for coordinating surveillance efforts during a public health emergency that has been shown to be effective in an actual public health emergency or a stress test.

4 Discussion

The purpose of this report is to provide an overview of identified issues and possible solutions to help strengthen the ability of EU Member States in assessing preparedness and planning for communicable disease threats in the future, through the development of shared metrics and indicators, based on the experiences of five countries during the first phase of the COVID-19 pandemic.

In the 'Methods' section, we referred to the public health emergency preparedness and response cycle and the ECDC logic model. This cycle is a classic process, which means that public health systems can employ the science of process improvement to ensure good preparedness. On the other hand, the ECDC logic model specifies the aims and objectives of public health preparedness, as well as the response capabilities and preparedness capacities needed to achieve them.

The implementation of this approach typically employs a quality management system (QMS) to ensure continuous improvement in preparedness and response processes that impact health outcomes. This report does not focus on specific process improvement models, but the one aspect that the various models in use have in common is the focus on measuring and assessing system performance [3]. For example, the International Organization for Standardization (ISO) has thousands of different standards across hundreds of organisational and agency sectors of commerce, business and government. The ISO certification provides an impetus to quantify system performance, since the basis of certification requires an organisation to have the ability to measure, evaluate and improve procedures in addition to meeting minimum standards (see Annex 1 for a more in-depth discussion of the ISO and other process improvement methods and related performance indicators). The findings in this report are intended to improve preparedness indicators, regardless of the specific QMS a country's PHEP system employs.

A high level of preparedness, informed by valid and reliable preparedness indicators, implies that an organisation has the capability and capacity to respond optimally to disasters and emergencies. On the contrary, a low level of preparedness signals significant deficits resulting in a poor response. Regarding the indicators used to evaluate quality management, the preparedness measurement process must take place prior to the implementation of the response measures. Furthermore, corrective actions must be guided by the outcomes of previous iterations of the quality improvement cycle.

The domains analysed in this project are based on the ECDC logic model and include testing and surveillance, healthcare sector coordination, and emergency risk communication. In the logic model causality flows in the direction that indicates that capacities enable response capabilities, which in turn help PHEP systems meet their objectives.

In this report, existing measurement tools are compared (HEPSA, JEE, GHSI) for *what* (e.g. which aspects of preparedness) and *how* they assess preparedness. The following overarching issues were identified:

- The COVID-19 pandemic required the EU Member States to develop new strategies, approaches and policies related to their PHEP systems and structures under pressure. These also had to be reviewed and revised as the pandemic evolved. The extent of revision and innovation required was not contemplated in existing measurement tools for preparedness.
- Existing preparedness indicators generally do not reflect a country's internal hierarchical structure of public health, healthcare, and other entities that influence emergency responses.
- Existing measurement tools for preparedness generally do not reflect the required coordination among different sections of the healthcare system, particularly at the hospital and population-based medicine.
- Existing preparedness indicators generally do not represent the challenges of scaling up a country's pandemic response.

Specific indications of issues missing from, or not adequately covered in existing preparedness measurement tools, particularly the HEP SA and JEE, are as follows:

- Being able to conduct testing at scale was critical in the early phase of the pandemic. This depended on: the ability of laboratories to develop a test for a new pathogen, the availability of supplies, having trained staff or the capacity to rapidly train new staff, and the existence of an electronic reporting network. Testing also depended on the flexibility and resilience of the public health system (especially the regulatory agencies) to approve a new test, to identify additional sources of laboratory capacity, and to develop guidance regarding which tests should be used and when.
- Providing timely national surveillance data was challenging in two respects: modifying existing infectious disease reporting systems to add a new 'notifiable disease', and adapting ad hoc surveillance systems (e.g. hospital capacity, syndromic surveillance).
- The preparedness indicators related to testing and surveillance used in the assessment tools (JEE and HEP SA) cover the main tasks, but do not address the ability of systems to scale up testing capacity, the importance and complexity of sub-national structures for surveillance and epidemiological investigation, or the challenges of adapting and modifying existing routine and ad hoc surveillance systems during the pandemic.
- Although three capabilities in the ECDC preparedness logic model (management of medical countermeasures, supplies and equipment, medical surge, and hospital infection-control practices) proved to be critical, they are not represented in existing measurement systems for preparedness.
- The ECDC preparedness logic model's 'preventive services' capability should be integrated by adding a new capability on the 'coordination of preventive, primary care and other outpatient services', defined as 'the ability to activate and strengthen – during an outbreak of a high impact infectious disease – public health and primary care services, coordinating all providers (public and private, out and inpatient health services as well as mental health and social support agencies) using integrated pathways between outpatient care and hospitals'.
- The emergency risk communication capability in the ECDC preparedness logic model was important during the COVID-19 response, but not completely represented in existing preparedness assessment tools. In addition, countries experienced difficulties in managing an epidemic of information, suggesting that the logic model should be expanded to include a fifth emergency risk communication capability: 'infodemic management'. This is defined as 'the management of 'an overabundance of information – some accurate and some not – that occurs during an epidemic'.

The specific indicators proposed in each capability area are summarised in Table 5.

Table 5. Proposed indicators for testing and surveillance, healthcare coordination, and emergency risk communication capability areas

Capability area	Proposed indicators
Testing and surveillance	
Laboratory analysis	<p>The ECDC logic model capability is appropriate, but 'laboratory analysis' may not be the best label to convey the concept of operating at scale, as well as the importance of testing capabilities for public health operations, situational awareness, risk assessment and characterisation.</p> <p>The proposed indicators should identify appropriate metrics from existing measure sets, including:</p> <ul style="list-style-type: none"> • laboratory services are available to test for priority health threats (from the HEP SA tool); • laboratory testing for detection of priority diseases, a specimen referral and transport system, an effective modern point of care and laboratory-based diagnostics, and a laboratory quality system (from the JEE tool). <p>A new indicator should be developed for assessing the possibilities for scaling up testing operations and handling large numbers of samples submitted for diagnostic purposes.</p>

Capability area	Proposed indicators
Surveillance and epidemiological monitoring	<p>The ECDC logic model capability is appropriate.</p> <p>The proposed indicators should identify appropriate metrics from existing measure sets, including:</p> <ul style="list-style-type: none"> • surveillance system measures from the HEPESA tool (see Table 1); • indicator and event-based surveillance systems; interoperable, interconnected, electronic real-time reporting system; analysis of surveillance data; syndromic surveillance systems, and reporting network and protocols in respective countries (from the JEE tool). <p>A new set of indicators should be developed related to:</p> <ul style="list-style-type: none"> • the existence of methods for monitoring and integrating data from a wide range of sources; • the importance and complexity of sub-national structures for surveillance and epidemiological investigation; • the challenges of adapting existing and developing new surveillance systems during the pandemic.
Risk characterisation	<ul style="list-style-type: none"> • Revise the ECDC logic model to integrate 'incident recognition' and 'epidemiological investigation', which are currently separate capabilities, and clarify the relationship to testing and surveillance.
Healthcare sector coordination	
Management of medical countermeasures, supplies and equipment	<p>The ECDC logic model capability is appropriate, but develop measurements indicating whether:</p> <ul style="list-style-type: none"> • products, equipment and drugs considered essential to deal with a public health emergency have been stockpiled and maintained in multiple storage sites distributed throughout the territory; • those responsible for procurement in emergency conditions have been identified; • several purchasing channels have been kept open for redundancy.
Medical surge	<p>The ECDC logic model capability is appropriate, but develop measurement indicating whether:</p> <ul style="list-style-type: none"> • an emergency plan to cope with medical surge has been developed; • hospital organisations have been designed to be flexible and scalable; • hospital facilities have been designed with redundancy (emergency reserves) in advance, i.e. more beds, staff and equipment than strictly necessary under normal conditions; • multi-purpose health personnel who can be used for different tasks according to needs (task shifting) have been trained; • a plan on how to return to normality has been developed.
Hospital infection-control practices	<p>The ECDC logic model capability is appropriate, but develop measurement indicating whether:</p> <ul style="list-style-type: none"> • infection control protocols for hospital healthcare facilities containing precautions to be observed by staff, patients and visitors have been developed, and all the entities have the necessary equipment available to implement the plan; • a plan to separate the flow of infectious patients (and suspected cases) from non-infectious patients has been developed for all healthcare facilities.
Coordination of preventive, primary care and other outpatient services	<p>Integrate the 'preventive services' capability in the ECDC logic model to include 'coordination of preventive, primary care and other outpatient services' and develop measurements indicating whether:</p> <ul style="list-style-type: none"> • emergency plans that identify tasks, responsibilities and procedures to be implemented in a health emergency have been prepared, with particular regard to protocols and telemedicine tools to treat patients at home; • health personnel working in the community have all the tools necessary to implement these emergency plans as well as their own stock of PPE; • outpatient healthcare professionals have been trained to coordinate and communicate with each other; • channels and tools to facilitate communication between healthcare professionals (both in and outpatient) and other emergency responders have been identified and operationalised.

Capability area	Proposed indicators
Emergency risk communication	
Communicate risk in a timely and transparent manner	<p>The ECDC logic model capability is appropriate, but develop measurement indicating whether:</p> <ul style="list-style-type: none"> • roles, responsibilities, and flexible procedures for a timely release of information to international, national and sub-national organisations have been established; • roles, responsibilities, and procedures for a timely release of information to the press and media agencies have been established; • multidisciplinary task forces have been created with the scope of enhancing coordination in communication efforts across government units; • processes and procedures for the release of information using social media by governmental institutions and governmental officials have been created; • a process for inter-unit collaboration aimed at incorporating the results of the risk assessment – including what is unknown – into public communication efforts has been established; • a web-based dashboard that can promptly be activated and updated to share information with the public has been developed.
Foster and maintain trust with the media and the public	<p>The ECDC logic model capability is appropriate, but develop measurement indicating whether:</p> <ul style="list-style-type: none"> • trusted channels of information based on the target audience have been identified; • trusted spokespersons based on their knowledge, role in public health institutions, and ability to convey information to the target audience have been identified; • the content of the communication has been tailored to informational needs and evolving science; • journalists and public health experts are trained on each other's field of work.
Communicate risk in a clear, consistent, and empathetic manner	<p>The ECDC logic model capability is appropriate, but develop measurement indicating whether:</p> <ul style="list-style-type: none"> • audience and expert intermediaries that are knowledgeable in the use of technical lexicon used by the target audience (i.e. trade organisations, industries, commercial entities) have been identified; • national and sub-national government agencies (i.e. regional public health entities) and other organisations (i.e. trade organisations) have been engaged to assure consistency in the delivery of the messages; • a mechanism to answer potential questions from the public and the media has been created and monitored to ensure clarity and to adapt the tone of communication; • a mechanism to develop empathic and culturally appropriate language that recognises the perspectives and feelings of the audience to whom the message is directed has been created.
Identify and address communication inequalities	<p>The ECDC logic model capability is appropriate, but indicators need to be developed to assess whether:</p> <ul style="list-style-type: none"> • data gathering mechanisms to understand informational needs and knowledge gaps across various segments of the population (i.e. polls, interviews, focus groups and expert opinions) have been identified; • mass communication channels and spokespersons based on the target audience have been identified; • venues and mechanisms for public interaction and information exchange have been established.
Manage the infodemic	<p>Add a new capability to the ECDC logic model and develop measurement indicating whether:</p> <ul style="list-style-type: none"> • organisations that will implement monitoring of misinformation (i.e. via social media monitoring) and assess informational needs (i.e. via polls, focus groups) have been identified; • strategies to reduce gaps in health and digital literacy have been implemented; • counter-messaging strategies have been identified; • mechanisms that allow communicators to be responsive and proactive in addressing the informational needs of the media and the population have been developed; • mechanisms to coordinate the management of mis/disinformation with governmental and non-governmental agencies have been developed.

The analysis in this report suggests that the type of measurement approach and format used in the JEE tool might be useful for the EU's preparedness assessment efforts. This would involve first developing a set of indicators to cover the areas identified in the analysis, and then for each of them creating a scoring system or scale similar to the one shown in Table 4.

4.1 Limitations

This analysis is limited to the first phase of the pandemic, before the initiation of vaccination programs in December 2020. The report focuses only on following issues that a preliminary review identified as important in Europe during that stage of the pandemic: testing and surveillance, healthcare sector coordination, and emergency risk communication. It has to be noted that coordination and communication within the public health emergency preparedness system, with other sectors such as education and civil protection, or at the international level are not addressed.

The analysis was limited to five countries, following the principle of including countries with different governmental systems that experienced the pandemic in diverse ways. A limitation in this regard is that this project was conducted with the EU Member States which were willing to commit to participation. This was difficult since the pandemic was still ongoing. The number of individuals who were available to be interviewed was also limited. However, the literature reviewed in peer-reviewed publications went beyond the five countries in some cases, and the convergence of issues raised both in the interviews and the literature suggests that no major issues were left unaddressed.

The interviews were conducted primarily with governmental officials in health agencies at the national level. Apart from a few exceptions, we did not speak to sub-national or local officials, or representatives of private-sector healthcare organisations, such as, doctors, nurses, other healthcare providers, or patients' organisations. Although some of these perspectives were represented in the published literature and by the interviewees, other issues may have been missed.

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Annex 1. Linking indicators for public health preparedness to a quality management system

Treating public health emergency preparedness (PHEP) as a process, as noted in the Introduction section, means that public health systems can employ the science of process improvement to ensure their systems are well prepared for emergencies. There are various process improvement models in use, but the one common aspect is the need to measure or assess system performance. As the old adage goes, 'what gets measured, gets done', so measuring the right constructs with valid and reliable indicators is critical. Building on this tradition, public health preparedness metrics can be compared to Donabedian's approach to healthcare quality measurement: outcome, process, and structure measures. However, as discussed, a different approach is needed for public health emergency preparedness.

Following the principles of process improvement, PHEP indicators of optimality should be part of the organisation's quality management system (QMS) to ensure that they can be used to continuously improve preparedness and response processes that impact health outcomes. A QMS is formalised such that documents, processes, procedures, and responsibilities for achieving quality policies and objectives can be utilised and evaluated. In the context of security and safety, the term 'preparedness' has been defined as 'a continuous cycle of planning, organising, training, equipping, exercising, evaluating, and taking corrective action to ensure effective coordination during incident response'. This definition underscores the affinity of the preparedness system to the more general quality management system. A high level of preparedness informed by valid and reliable preparedness indicators implies that an organisation has the capability and capacity to respond optimally to disasters and emergencies, while a low level of preparedness signals significant deficits that result in a poor response. Moreover, like measurements used to evaluate quality management, the preparedness measurement process must take place prior to the implementation of the response actions. Furthermore, corrective action must be guided by the outcomes of previous iterations of the quality improvement cycle. The QMS must also provide a way to coordinate and direct the organisation's activities to meet the operational and regulatory requirements to improve effectiveness and efficiency for continuous quality improvement.

A.1 Example: International Organization for Standardization (ISO)

The most popular family of standards used to demonstrate the ability to consistently provide reliable and effective services are those developed by the International Organization for Standardization (ISO) [62]. While ISO has thousands of different standards across hundreds of organisational and agency sectors of commerce, business and government, the ISO 9000 series is the only standard in the series to which organisations can officially certify. Certification provides an impetus for quantifying quality, since the basis of certification requires an organisation's ability to measure, evaluate and improve processes in addition to meeting minimum standards. Internal and external audits examine the ability of an organisation to implement a continuous quality improvement system. Several findings in this study support the characteristics of flexibility, adaptation, and the ability to change as needed. These characteristics are fundamental to quality improvement and are woven into the fabric of the QMS.

The findings of this project can be useful for informing the COVID-19-related standards currently being drafted by ISO member technical committees, as well as other COVID-19 resources made available through ISO. Likewise, the project findings may also be framed within the seven ISO 9001 principles (2015): leadership, engagement of people, process approach, improvement, evidence-based decision making, relationship management, customer focus.

Within ISO, standards are developed by groups of experts called technical committees. These experts are put forward by ISO's national members. Each country must contact their respective national standards body which is an ISO member to see whether there is interest in pursuing the areas and indicators researched as part of this project. Going forward, alignment with the ISO 9001 series as well as the more specific COVID-19 standards could inform future work towards building a more structured, international quality evaluation system for assessing the capabilities and capacities within the context of public health planning, preparedness and response.

Regarding ongoing work done by ISO in the area of quality standards for COVID-19, in June 2021, ISO created technical committees concerned with specific aspects of the response to COVID-19. This related to products such as protective clothing, lung ventilators, medical devices, respiratory medical devices, biocompatibility of breathing gas pathways, security and resilience, risk management, occupational health and safety management, and medical electronic equipment [63]. Most of these standards, however, related to specific, limited components of healthcare delivery and public health systems, rather than the entire PHEP enterprise in a country.

Currently, ISO also provides information featuring national resources developed by ISO members to support the public health and healthcare response to COVID-19 [64]. The Strategic Alliance and Regulatory Group of ISO's Committee on Conformity Assessment (CASCO) surveyed those working in conformity assessment to understand their challenges related to COVID-19 [65].

New and upcoming ISO standards that can help establish the right course of action, improving recovery, bolstering resilience, and saving lives are currently being developed by ISO technical committees [66]. For example, with the safety of both the healthcare provider and the patient in mind, ISO technical committee ISO/TC 304, Healthcare Organization Management [67], established a working group (WG 4) to focus on how best to cut the chain of transmission in situations of a pandemic. WG 4, Pandemic preparation response, aims to develop standards that will help healthcare organisations run safe and fast testing facilities with the ability to rapidly quarantine and treat patients without increasing infection rates. According to the WG 4, the COVID-19 pandemic revealed 'the importance of developing and maintaining healthcare systems that are not only able to handle such crises, but that can spring into immediate action to reduce the spread of infectious diseases quickly and effectively at the first signs of an outbreak'.

Three standards currently being worked on by the group are: ISO 5258 (drive-through screening stations for infectious disease control) [68], ISO 5472 (walk-through screening stations for infectious disease control) [69] and ISO 5741 (pandemic response in residential treatment centres) [70]. The WG 4 believes that 'these standards will provide an effective infection control strategy by giving health workers the ability to quickly identify, isolate and treat patients through rapid examination'. Future collaborations with the members of ISO could have far-reaching impacts as currently 165 of the world's 195 countries have membership in ISO with 124 of these being member bodies that can develop and vote on standards.

A.2 The ECDC logic model and Donabedian's approach to healthcare

In the ECDC logic model for PHEP in the EU Member States, the outcome indicators, or the objectives of the emergency response consistent with the Donabedian's definition of outcomes, are: a) earliest possible identification of event; b) early and effective response, including minimising morbidity and mortality, limiting spread of disease, minimising social disruption, and minimising infrastructure and environmental damage; and c) earliest possible recovery and return to normal.

The measurement of public health preparedness must precede the response to a disaster or an emergency. In contrast, outcomes are the end results of the response, and are used explicitly to evaluate the success of the response once it occurs. The success of the response to a disaster or an emergency is often measured by health outcomes, such as morbidity and mortality, but can also be measured by harm to the environment, economic impact, and more subjective measures of human suffering.

Furthermore, unlike regular healthcare operations, in which many patients are treated with indicated treatments for specific conditions every day, large-scale public health emergencies are rare and singular events. Consequently, outcomes are difficult to measure statistically. Furthermore, achieved outcomes such as the total number of cases or deaths do not necessarily reflect preparedness efforts for multiple reasons. Firstly, preparedness systems that exist may not have been deployed for political decisions or because of policy decisions specific to the event. Secondly, factors other than preparedness influence outcomes. These include: chance occurrences (e.g. Italy being the first country in Europe to see substantial numbers of COVID-19 cases) and population structure (share of elderly people and related morbidity patterns, socio-economic circumstances, etc). Unlike in healthcare quality, there is no opportunity for statistical risk adjustment. Consequently, outcomes cannot be used as *preparedness indicators*.

In particular, epidemiological assessment of the impact of COVID-19 (e.g. case counts, hospitalisations, attributed deaths) per se *are not* preparedness metrics; they are calculated only after the event. So, logically they cannot indicate preparedness. However, policy decisions should be based on the expected impact of these issues, and having systems in place to prepare such assessments when needed, during the pandemic *is* a preparedness capacity. Whether these systems exist and how well they perform *are* preparedness indicators.

Capabilities (process) indicators

The process indicators in the Donabedian approach are represented by the ECDC logic model's *capabilities*, what the system can and does achieve in practice, during an emergency response. For example, the first group of capabilities relate to 'detection and assessment', specifically 'incident recognition', 'risk characterisation', 'epidemiological investigation', 'surveillance and epidemiological monitoring', 'laboratory analysis' and 'environmental monitoring'. The other four groups of capabilities are: 'policy development, adaptation, and implementation', 'health services', 'coordination and communication (within the public health emergency preparedness system)', and 'emergency risk communication (with the public)'.

In healthcare, process indicators reflect what the system can and does achieve in practice (e.g. deliver preventive services, such as providing aspirin to those suffering heart attacks on arrival in the emergency department, etc). In preparedness, there may be a difference between what the system does in regular practice (e.g. complete and timely reporting of notifiable diseases), and can do in an emergency (identify, report, and characterise first cases of a novel pathogen). Consequently, there are limits to the validity of process indicators as *preparedness metrics*. Nevertheless, if regular practice is characterised by poor performance (e.g. in peace time when occasional small outbreaks occur), the system is not likely to perform better in an emergency. On the other hand, actual public health emergencies, like the COVID-19 pandemic, provide a rare opportunity to assess a system's capabilities in practice.

Capacity (structure) indicators

The structure indicators in the Donabedian approach correspond to the *capacities* in the ECDC logic model. As in the measurement of the quality of healthcare, these capacities represent organisational characteristics that are in place before an emergency occurs. For example, the capacities corresponding to the 'detection and assessment' capability area include: testing capacities, case definitions and protocols, electronic reporting systems for notifiable diseases connecting the local, regional and national, capacity to analyse surveillance data, characterise risks, number of epidemiologists and other relevant professionals, and processes to report to and consult with ECDC and WHO.

As emergencies are rare and singular, outcome and process indicators are generally not available or useful for assessing preparedness. Consequently, most preparedness metrics focus on capacities, i.e. organisational characteristics. However, capacity metrics are problematical, because there is relatively little evidence to connect capacities to capabilities and outcomes.

While the measurement of preparedness does not include these measures of outcomes, the preparedness indicators themselves rely on the information gained from the outcomes of previous responses to establish their validity and reliability. As with other quality indicators, predictive validity is especially important. The term 'predictive validity' refers to the extent to which a preparedness indicator score can be used to predict the success of the response to a disaster or emergency in the future. In healthcare operations, statistical studies have established, for instance, that higher nurse staffing ratios are associated with better outcomes, the immediate use of aspirin improves outcomes in patients suffering a heart attack, etc. Studies demonstrating the relationship between preparedness capacities, a system's capabilities, and realised outcomes are rare. Consequently, most preparedness metrics are based on professional judgement informed by standard public health operations and previous emergencies. Therefore, it is difficult to know a) what capacities are important to measure; b) how to formulate metrics in quantitative or qualitative terms; and c) how to determine appropriate targets, e.g. how many epidemiologists per capita are needed.

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