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Healthcare services re-organization based on lessons learned during COVID-19 pandemic. Conceptual frameworks and measurement and assessment tools for public health emergency preparedness.

Presentata da: Dott. Stefano Guicciardi

Coordinatore Dottorato

Prof.ssa Susi Pelotti

Supervisore

Prof.ssa Paola Rucci

Co-Supervisore

Prof.ssa Maria Pia Fantini

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ABSTRACT

Public health emergency preparedness (PHEP) is a core element for health systems, which involves a coordinated and continuous process of planning and implementation based on measuring performance and taking corrective actions.

The COVID-19 pandemic highlighted critical areas within health systems, with the need of a revision of previous logic models and the implementation of new assessment tools for PHEP.

On this basis, the European Union (EU) promoted an evolution of the legislative context on PHEP and the mandate of its main institutions, mainly the European Centre for Disease Prevention and Control (ECDC).

Building on collaborative efforts between international organizations and research centers, the aim of the current PhD thesis is to study and upgrade conceptual frameworks of PHEP in response to pandemic emergencies and identify assessment models relating to the organization of care pathways, with a specific focus on the hospital setting and on the integration with primary care systems related to the rearrangements induced by the COVID-19 pandemic.

The findings of the thesis provided elements for the revision of the current ECDC Logic Model for PHEP and evidence for improvements in the area of healthcare coordination; additionally, they suggested methodological approaches for standardized assessment and evaluation tools for PHEP systems within the EU.

SUMMARY

INTRODUCTION

Public Health Emergency Preparedness

Public health emergency preparedness (PHEP) represents a cornerstone of global health security.
It may be defined as the capability of the public health and health care 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.(1)

In an era marked by heightened mobility, urbanization, and interconnectedness, the world has witnessed a surge in public health threats ranging from emerging infectious diseases to bioterrorism. The onset of the 21st century underscored the profound implications of these threats, emphasizing the need for coordinated, evidence based PHEP approaches to deal with health emergencies of global concern.(2)
The 2003 outbreak of severe acute respiratory syndrome (SARS) demonstrated the rapidity with which diseases can traverse borders, impacting both health and economies.(3)
Subsequent global health emergencies, including the H1N1 influenza pandemic in 2009, the West Africa Ebola outbreak from 2014 to 2016, and the Zika virus epidemic in 2016, each presented unique challenges, showing gaps in preparedness and response capabilities.(4),(5)
However, the COVID-19 pandemic, which began in late 2019, highlighted the importance of PHEP in unprecedented ways. The pandemic's widespread morbidity, mortality, and socio-economic disruption reiterated that effective preparedness is not just a health necessity but a crucial socio-economic investment.(6)

Despite advancements in technology and knowledge, many Nations grappled with healthcare system overloads, lack of protective equipment, and inadequate testing capacities. The evolution and enhancement of PHEP frameworks have been driven by these experiences and lessons learned from each event. Incorporating multifaceted strategies, from surveillance, community engagement, to resource management, PHEP acknowledges the importance of a holistic, multi-sectoral approach.(1)
Yet, despite strides in theory and practice, gaps persist, and challenges remain.

Resilience in the health systems

Resilience, a concept with its roots deeply embedded in ecology, psychology, and even systems theory, has emerged as an indispensable framework within public health over recent years. Originating from Holling's (1973) foundational ecological studies, resilience was posited as the capacity of a system to absorb disturbances and continue to maintain its functions.(7)
This understanding was later co-opted by developmental psychologists to interpret individual capacities to rebound from adversities.(8)

Given its multidisciplinary context, application of a narrow definition can be problematic and in health systems research wider dimension and diverse experiences should be considered, from sudden events like infectious disease outbreaks and natural disasters to ongoing issues like chronic illnesses and escalating healthcare expenses.(9)

Contemporary public health literature, thus, extends this notion from an individual or ecosystem's ability to rebound to a system's capability to anticipate, adapt to, and recover from shocks, especially in the context of global health threats, such as pandemics, climate change, and socio-political upheavals.(10)

The transition from conventional health strategies to resilience-based approaches stems from the realization that health systems globally are frequently pushed to their limits by unexpected crises. Recent outbreaks, like the COVID-19 pandemic, revealed the critical need not just for reactive but proactively resilient health systems, capable of anticipating potential threats, possessing robust response mechanisms, and ensuring rapid recovery post-crisis, with challenges in measuring these latent properties.(11)
However, resilience in public health is not limited to response mechanisms. It embraces a holistic view, accounting for the social determinants of health, and recognizes that community structures, socio-economic factors, and political landscapes play pivotal roles in shaping resilience at both individual and system levels.(12)

One ground-breaking approach is the focus on “community resilience” within public health strategies. Studies show that communities with robust social networks, active community engagement, and access to local resources demonstrate better health outcomes during and after crises, emphasizing the significance of community-led interventions in building public health resilience.(13)

The 2014 Ebola outbreak in West Africa offered compelling insights into this. Communities with active engagement strategies, where individuals were not just recipients but active participants in health interventions, showcased better containment and recovery rates.(14)

Further, resilience thinking in public health acknowledges the complex interplay between individual and systemic resilience. While individuals might possess innate capacities to navigate health adversities, systemic factors such as access to healthcare, quality of medical services, and socio-political support structures profoundly influence individual resilience levels. For instance, Norris et al. identified four primary adaptive capacities that impact community resilience in the face of adversities: economic development, social capital, information and communication, and community competence.(15) These dimensions emphasize that true resilience extends beyond mere infrastructure or resources, and it's rooted in community dynamics, relationships, trust, and collective action.

As intricate global challenges arise the need for embedding resilience thinking within public health frameworks intensifies. However, it's crucial to interpret resilience not as a fixed endpoint but as a dynamic dimension, not aimed at developing systems that are resistant to shocks but adaptive, flexible, and robust health structures capable of navigating uncertainties with agility and foresight.

The convergence and integration of PHEP and resilience

The intersection of PHEP with the notion of resilience has gained considerable attention in the wake of recent global health crises. Historically, PHEP emerged as a set of strategic and coordinated activities that focus on preparing for and responding to events that pose a severe threat to public health, such as pandemics, bioterrorism, and natural disasters.

Its cornerstone lies in the anticipation, rapid response, and efficient coordination of resources and interventions: PHEP focuses on the measures taken in advance to mitigate the impact of public health emergencies and to ensure a timely and effective response. It involves developing plans, procedures, and capacities to respond to emergencies and to reduce their impact on individuals and communities. PHEP is focused on systems, including early warning and surveillance systems, contingency and response planning, and the provision of medical and other essential services to affected populations.

Resilience, however, expands this view. Rooted deeply in socio-ecological systems thinking, as already mentioned, it pertains to the ability of systems, communities, and individuals to absorb shocks, adapt, and transform in the face of adversities.(16)

In the realm of public health, resilience encompasses social, economic, environmental, and institutional as well as primarily health system dimensions, enhancing the adaptive capacity of individuals and communities to cope with the impacts of public health emergencies, in terms of promoting social cohesion, improving communication and information sharing, and building trust between individuals and institutions, while economic resilience in public health involves building the capacity of individuals and communities to adapt to the economic impacts of public health emergencies, including job loss, income reduction, and economic disruption. (17)

While resilience and preparedness are both essential components of public health emergency management, they have different meanings and implications. Resilience is a holistic concept that emphasizes the importance of addressing the root causes of vulnerability and building the capacity of individuals, communities, and systems to cope with the impacts of public health.
Resilience includes effective political leadership, interpersonal trust, trust in government institutions, and similar factors that Bollyky and colleagues, as well as other authors, have found to have been critical to good COVID-19 outcomes.(18)

In some sense, resilience is a product of preparedness together with good governance and leadership and trust in institutions. Kahn and colleagues, for instance, have developed a resilience framework for PHEP that is similar to the Logic Model for PHEP in EU Member States afterwards described, but with an enhanced role of governance and leadership and ethics and values.(19)(20)(21)

Overall, the confluence of these two domains represents a novel paradigm in global health policy and planning. It recognizes that in our interconnected world, with complexities driven by factors like climate change, urbanization, global mobility, and socio-political dynamics, mere preparedness may not be sufficient.(22) Adaptive health systems —which are not only prepared for unexpected events but can also effectively respond, learn, and evolve post-crisis— are needed. The COVID-19 pandemic served as a stark illustration of this, where health systems with traditionally robust PHEP infrastructure struggled if they lacked systemic resilience.

Integrating PHEP and resilience invites a multi-layered approach to health system strengthening. It promotes a proactive stance, primed for emerging threats, while also ensuring adaptability and recovery in post-crisis scenarios. Such a holistic view emphasizes not just on the health outcomes but also on social, economic, and political dimensions, underscoring the interconnectedness of health with other sectors.(23)

Furthermore, the value of community engagement emerges prominently in this merged perspective. While top-down measures are integral to PHEP, resilience accentuates the importance of community agency, local knowledge, and grassroots initiatives.(24) For instance, during the Ebola outbreak in West Africa, community engagement was instrumental in turning the tide, marking a practical testament to the amalgamation of preparedness and resilience in action.(25)

Operationalizing this integrated concept requires embracing a culture of continuous learning, interdisciplinary collaboration, and adaptive governance in health systems in which traditional metrics, primarily outcome-focused, should be combined with indicators capturing long-term resilience, adaptive capacity, and systemic robustness.

This is especially true for resilience, that can be seen as a latent characteristic of a system. It can be assessed after an event, for instance COVID-19, in terms of cases and mortality, costs or unmet health needs but in practical terms, the indicators of resilience that can be measured in advance appear to be similar to preparedness measures. For example, Rajan and colleagues have shown how the European Observatory's Health System Performance Assessment (HSPA) Framework for Universal Health Coverage can be used to show how strengthening health systems can help to create resilience to withstand shocks like the COVID-19 pandemic.(26)

Many of its dimensions relate to preparedness, such as the existence of surveillance methods to alert health systems to the epidemiological changes or mechanisms to reassign health care professionals to new roles and places as needed, ensuring enough personal protective equipment to protect front-line workers.

However, the closest that the HSPA framework comes to good governance and leadership as well as trust in institutions is through items such as the ability to collaborate between different government sectors to ensure consistent policy implementation and the existence of mechanisms for key

stakeholders to contribute to response planning that still represent a challenge in their actual implementation.

In sum, the integration of PHEP and resilience offers a forward-looking, comprehensive blueprint for health systems of the future and is important for ensuring effective disaster risk reduction and management. As health threats grow in complexity and unpredictability, this integrated and complementary perspective ensures not just survival but a thriving, robust system capable of weathering multifaceted challenges.

Conceptual framework for measuring PHEP: the ECDC Logic Model

Assessing preparedness poses significant challenges due to the infrequency of serious public health emergencies and cross-border outbreak events. These rare occurrences provide limited opportunities for direct observation and after-action reviews to evaluate outcomes. Additionally, each event is unique and context-specific, making it impossible to apply statistical approaches commonly used in healthcare settings, such as post-surgical mortality or the proportion of patients receiving preventive services.

The complexity and multifaceted nature of effective public health emergency responses further complicate retrospective assessments. Without a counterfactual (i.e., an alternative response scenario), it's challenging to identify the optimal response for a specific situation, because what works well in a community may not be equally effective in others.(27)

PHEP systems vary significantly across EU countries, involving multiple jurisdictions and disciplines. National, sub-national, and local components within hierarchical public health agencies play crucial roles. Cross-border outbreaks require collaboration among the public health agencies of different countries, adding to the complexity.

Various entities, whose roles differ among countries, support public health preparedness, including healthcare providers, agricultural and environmental protection agencies, civil protection agencies, educational institutions, and law enforcement. Some of these entities may not even consider themselves as part of the public health response. Additionally, large-scale events often activate emergency operations centres (EOCs) under the control of government ministries or heads of state.

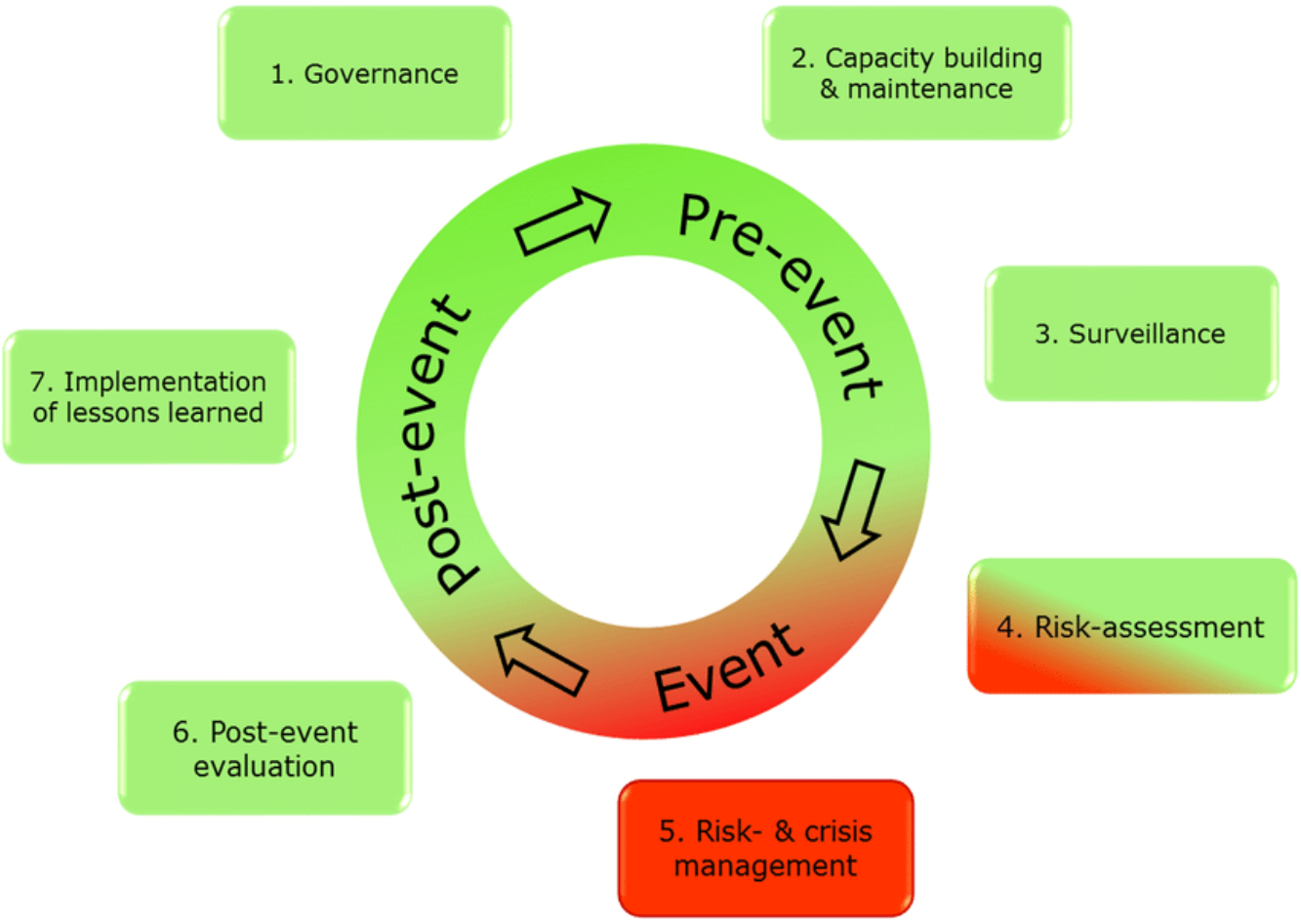
Communities and civil society also contribute, resulting in a complex landscape of stakeholders with varying degrees of involvement and influence.

This diffusion of responsibility and accountability further complicates the measurement of performance and the allocation of responsibility among partnering entities.(28)

The European Centre for Disease Prevention and Control (ECDC) follows a preparedness cycle with seven stages, as depicted in Figure 1, aligned with the approach adopted by the World Health Organization (WHO).(29) (30)

Assessments can occur at two key stages: during the pre-event phase (stage 2) to identify and strengthen capacity gaps and during post-event evaluations (stage 6) to focus on improving deficient capacities for future events.

Figure 1: ECDC Preparedness cycle

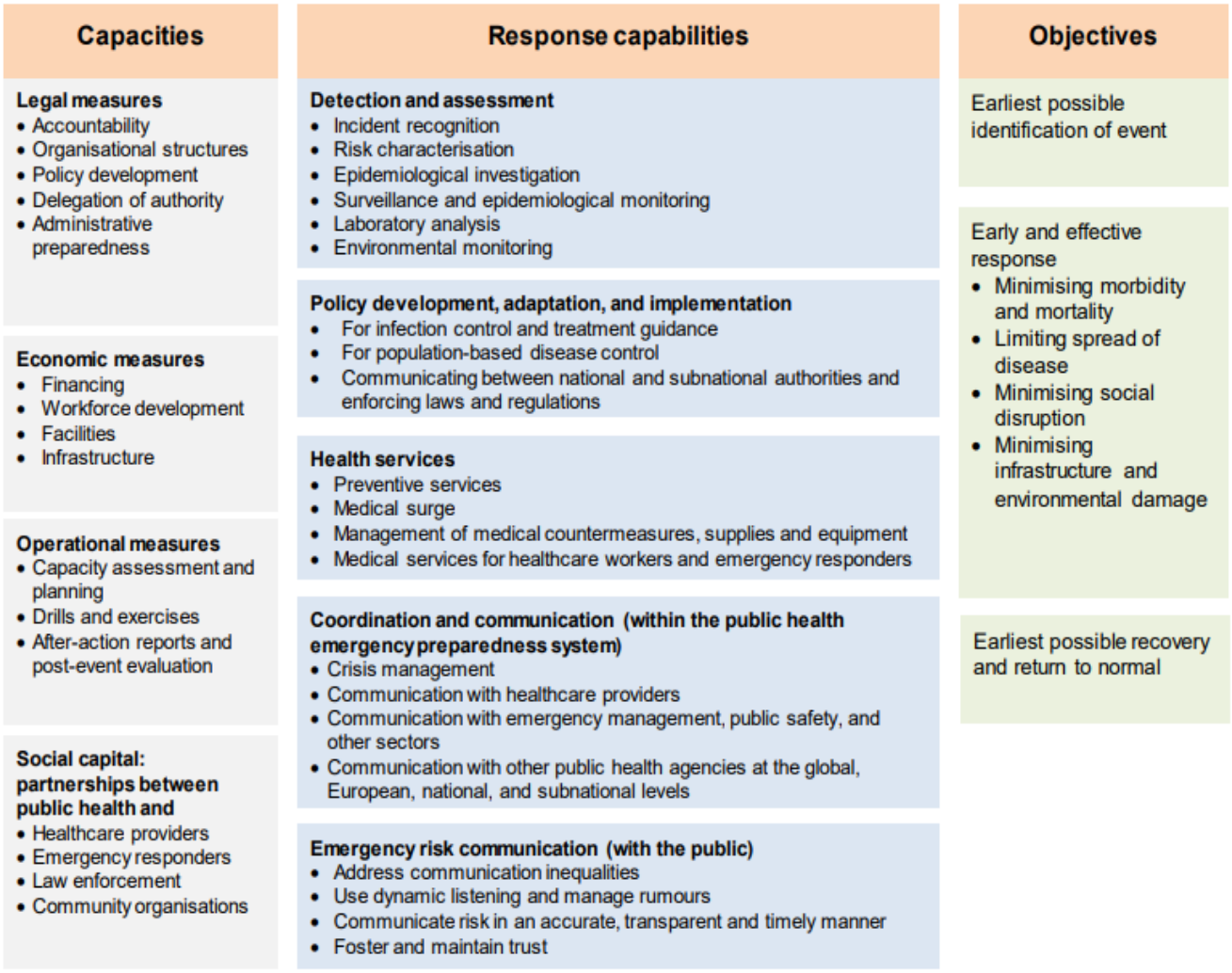


In order to organize the approach to these measurement challenges, on the basis of scientific evidence, experiences of public health practitioners and analyses of public health emergencies, the ECDC developed a “Logic Model” that specifies the aims and objectives of public health preparedness, as well as the response capabilities and preparedness capacities needed to achieve them (Figure 2).

The ECDC's Logic Model differentiates between measurements of preparedness capacities and response capabilities.

Similarly to Donabedian's approach to healthcare quality measurement, capacities are somewhat analogous to structural measures, while capabilities are akin to process assessments.(31)

Figure 2: ECDC Logic Model



Capacities encompass the resources such as infrastructure, existing response mechanisms, trained personnel, and other assets that a public health system relies on. Much of what public health preparedness organizations do between events, such as planning, training, and acquiring equipment, aims to build capacity for future emergencies.

For instance, the capacities related to the detection and assessment aspect of response capabilities include testing capacities, case definitions and protocols, electronic reporting systems for notifiable diseases connecting local, regional, and national levels, analytical capabilities for surveillance data, risk characterization, the number of trained epidemiologists and other relevant professionals, and established procedures for reporting to and collaborating with European and international organizations like ECDC and WHO.

Response capabilities, conversely, describe the actions a public health system can effectively undertake to identify, characterize, and respond to emergencies. This includes conducting surveillance and epidemiological investigations, providing diagnostic testing and vaccines, ensuring healthcare service surge capacity, communicating risks to the public, and coordinating responses through an effective incident management system. Capabilities are latent characteristics of PHEP systems best assessed during actual emergencies or situations where the PHEP system responds to an emergency.

Outcomes, in the end, are used to gauge the quality of the PHEP response and can guide improvements by enhancing specific capacities and capabilities. Outcomes such as morbidity and mortality are measurable during an actual event but are not suitable as preparedness indicators since they only become available after the event has occurred.

Furthermore, the Logic Model outlines the prospective relationship between capacities, capabilities, and the objectives of a PHEP system. These objectives include the earliest possible identification of an event, an early and effective response to minimize morbidity, mortality, disease spread, social disruption, infrastructural and environmental damage, and enabling the earliest possible recovery and return to normal.

The relationships within the Logic Model enable planners to determine the necessary steps to achieve these objectives ahead of an event.

The role of the European institutions in the context of PHEP

European institutions have, over the decades, increasingly positioned themselves as pivotal players in the landscape of public health emergencies, with their roles expanding and evolving in tandem with the complexities of emerging health crises. The founding treaties of the European Union (EU) articulated a limited role in public health, rooted in a respect for the national sovereignty of member states. The Maastricht Treaty (1992) established public health as a matter of EU concern, but the nature of this interest was largely collaborative, premised on complementing national initiatives rather than leading or replacing them.(32)

However, with the changing dynamics of global health and the transboundary nature of health threats, the Treaty of Amsterdam (1997) ushered in a more integrated perspective by emphasizing the importance of safeguarding human health across all sectors of community action.

The challenges posed by health emergencies in the early 21st century, notably the SARS outbreak in 2003, starkly revealed the vulnerabilities of piecemeal national responses. The swift spread of infections across borders illuminated the need for a robust, coordinated European response mechanism.(33)

This recognition led to the establishment of the Health Security Committee (HSC), and subsequently, the Decision 1082/2013/EU, which established a comprehensive framework for managing serious cross-border health threats, signifying the EU's commitment to a unified response strategy.(34)

A cornerstone of this evolving European strategy has been the formation and empowerment of specialized agencies. The ECDC, instituted in 2004, has been fundamental in offering a consolidated European response through surveillance, advice, and rapid risk assessment during health crises.

Parallelly, the European Medicines Agency (EMA), founded even earlier in 1995, plays a vital role in the scientific assessment of medicines, ensuring their safety and efficacy, a role that becomes particularly crucial during health emergencies.

Nonetheless, even with these structures in place, the EU found itself grappling with the multifaceted challenges of the COVID-19 pandemic. As the virus spread with alarming rapidity across member states, European institutions faced criticism for perceived inadequacies in their initial response.

Yet, agencies like ECDC and EMA showcased their relevance by offering valuable scientific insights, guidelines, and facilitating the accelerated approval of COVID-19 vaccines.

In reflection and in preparation for future health emergencies, the European Commission has proposed and established the Health Emergency Response Authority (HERA). Envisioned as a dynamic institution, HERA is geared towards ensuring rapid, coordinated, and advanced response mechanisms during health emergencies, serving as a bridge between scientific innovation and its practical deployment. The conceptualization of HERA underscores the EU's commitment to evolve and adapt, learning from past challenges to bolster its health emergency framework.

Moreover, the EU has actively sought to align its strategies with broader global health objectives, cultivating a robust partnership with the WHO. This partnership, exemplified by the updated Memorandum of Understanding in 2020, emphasizes collaboration in areas of health security, strengthening health systems, and ensuring universal health coverage, reflecting the EU's recognition of health as a global public good.

Further reinforcing its commitment to public health, the EU has channelized significant resources towards health research and innovation. Horizon 2020, a flagship initiative, exemplifies this commitment by earmarking substantial funds towards pressing health challenges, thereby showcasing the EU's strategic foresight.
Overall, the trajectory of European institutions in the context of public health emergencies vividly mirrors the evolving challenges and imperatives of global health.(35)
From its foundational treaties to the creation of specialized agencies and the envisioned HERA, the EU demonstrates an adaptive and resilient approach.
While the path is fraught with challenges, the EU's dedication to health both within its borders and globally signals a robust commitment to public health, grounded in the principles of solidarity, cooperation, and innovation.

The European Centre for Disease Prevention and Control (ECDC)

The ECDC has undergone profound transformations in its role and operations since its establishment, reflecting the dynamic nature of global health challenges. Founded in 2004 as an EU agency with a mandate to strengthen Europe's defence against infectious diseases, the ECDC was a culmination of efforts to ensure a more harmonized and robust response to disease threats within Europe (ECDC, 2021). These early ambitions were driven by a recognition that while the 20th century had witnessed unprecedented advances in healthcare, it also underlined the transboundary nature of health threats, such as the SARS outbreak in 2003, which revealed gaps in coordinated responses among nations.(36)

A core aspect of the ECDC's role from its inception has been surveillance. Recognizing the essence of data-driven decision-making in public health, the ECDC pioneered the development of the European Surveillance System. This data platform, which aggregates and analyses infectious disease data from across Member States, has become instrumental in shaping Europe's response to various outbreaks.(37)

However, the role of the ECDC is not merely limited to surveillance. Over the years, it has established itself as a hub of expertise, guiding policy decisions and public health practices across the EU.

The H1N1 influenza pandemic in 2009, for instance, highlighted the ECDC's evolving role in risk assessment, communication, and the dissemination of best practices. Through rapid response mechanisms, the ECDC ensured that Member States had timely and accurate information to guide their strategies.(38)

The evolution of the ECDC's role can also be discerned in its approach to emerging health threats. During the 2015-2016 Zika virus outbreak, the ECDC went beyond immediate response strategies. While it played a vital role in risk assessment and the provision of immediate guidance on vector control and case management, it also stressed the importance of longer-term measures such as research into vector-borne diseases and potential control strategies.(39)

The unprecedented challenges posed by the COVID-19 pandemic further underscored the ECDC's pivotal role. In an era marked by information overload, the ECDC emerged with its key role in producing trustworthy data and analysis. Regular situation updates, risk assessments, and technical guidance became invaluable resources for policymakers and health professionals alike.

Collaborating closely with global health entities, the ECDC was central to the development and dissemination of diagnostic tests, and subsequently, in the rollout and monitoring of vaccination campaigns.(40)

Vaccination, in particular, has seen the ECDC play a more pronounced role in recent years. The ECDC's Vaccine Schedule platform, an interactive tool providing an overview of vaccination recommendations across the EU, is a testament to the agency's broader commitment to preventing outbreaks of vaccine-preventable diseases. By centralizing such information, the ECDC not only fosters knowledge sharing but also encourages harmonization in vaccination strategies across Member States, ensuring a more cohesive public health approach.

The experience of the ECDC has not been without challenges. Critics have sometimes pointed to its mandate as being too expensive, suggesting potential overlaps with roles of national public health institutions and even other international bodies like the WHO.
Questions have also arisen concerning the timeliness and responsiveness of some of its surveillance mechanisms, arguing that bureaucratic intricacies might impede real-time action.
Nonetheless, even amidst these critiques, there is a broad consensus on the indispensable nature of the ECDC in the European public health ecosystem.

In summary, tracing the trajectory of the ECDC reveals an institution that has not only adapted to the shifting sands of global health challenges but has also proactively shaped Europe's responses to them. From its nascent days focused primarily on disease surveillance to its current multifaceted role encompassing research, policy guidance, communication, and more, the ECDC stands as a testament to the importance of regional cooperation in public health. As infectious disease threats continue to evolve in complexity and scale, the ECDC's role as a sentinel and guide for Europe's public health responses will undoubtedly remain crucial.

Overview of the impact of COVID-19 on the European Union Public Health System

When the World Health Organization declared the outbreak of COVID-19, caused by the SARS-CoV-2 virus, a Public Health Emergency of International Concern in January 2020, the impact quickly spread globally, affecting millions, and disrupting nearly every facet of daily life.
In the European Union, which comprises 27 Member States, the pandemic posed a significant challenge, testing the mettle of the region's public health systems.
The response and impact varied greatly among each country, underlining both commendable strengths and concerning vulnerabilities.
Nations such as Italy and Spain experienced exponential rises in cases, and their health systems were soon under duress. In particular, Northern Italy's Lombardy region faced an overwhelming surge of patients, a situation that rang alarm bells across the EU.(41)

A pressing issue that emerged was the availability and allocation of resources, particularly for intensive care. Across the EU, there was a palpable shortage of critical care facilities, ventilators, and Personal Protective Equipment (PPE). Health professionals at the front line, confronting a hitherto unknown viral adversary, found themselves grappling with scarce resources.(42)

Moreover, the discrepancies between member states in terms of healthcare infrastructure, economic robustness, and crisis preparedness became starkly evident. While Germany, with an abundance of ICU beds and despite its decentralized healthcare system, managed example, the early crisis relatively well, other states with fewer resources faced significant challenges.(43)

However, beyond the immediate health crisis, the pandemic revealed deeper systemic issues within the EU's public health paradigm. The lack of a centralized, cohesive pandemic response strategy became clear. Although the ECDC played a crucial advisory role, individual nations ultimately tailored their responses based on national conditions, leading to a patchwork of measures across the continent.
This fragmentation was evident in several areas. Border controls, typically porous within the Schengen Area, saw restrictions, a move that resonated with the challenge of balancing public health with the EU's foundational principles of free movement and integration.
Similarly, the procurement of medical equipment became a contentious issue, with countries initially competing against each other, before the European Commission stepped in to centralize purchases.

A notable aspect of the EU's response was the show of solidarity and mutual aid. Transfers of patients across borders, shared medical supplies, and collaborative research efforts epitomized the spirit of European integration. The EU's collaborative research and commitment were also evident in the vaccine development and subsequent rollout, with the EMA playing a pivotal role in approvals, and the EU Commission coordinating procurement.

Looking beyond the immediate crisis, the pandemic also influenced broader health policy debates within the EU. The emphasis shifted to strengthening healthcare systems, focusing on prevention, bolstering research, and ensuring universal health coverage. The pandemic has also accelerated digital transformations in healthcare, with telemedicine and e-health solutions gaining prominence.(44)

In sum, while the COVID-19 pandemic has posed unprecedented challenges to the EU's public health system, it has also presented an opportunity for a general revision of the EU PHEP system.
The lessons derived from this crisis, both in terms of immediate responses and long-term strategies, led to an overall revision of the EU legislative mandate with the potential to shape the future trajectory of public health within the European Union.

Evolution of the legislative mandate for measuring and assessing public health emergency preparedness

In 2013, the EU adopted the already mentioned Decision 1082, addressing serious cross-border threats to health. This reflected the collective responsibility recognized by the Member States to amplify and sustain their ability to detect, evaluate, inform, and address international public health emergencies.

The Decision emphasized the importance of consultation for promoting the interoperability of national preparedness plans in accordance with global standards, all the while respecting the competence of Member States to shape their health infrastructures.

As part of its mandates, Decision 1082/2013/EU obligated Member States to periodically update the European Commission about their status of preparedness and reaction planning. The role of the Health Security Committee (HSC) was to compile this data, ensuring its dissemination among the Member States.

Pursuant to this, Article 4 of Decision 1082/2013/EU initiated the creation of a reporting template for Member States to be utilized triennially with the following information:

- elements that states are mandated to present to the WHO under the International Health Regulations (IHR);
- initiatives ensuring the interoperability between health sectors and other critical sectors during emergencies, underscoring the coordination mechanisms for cross-sectoral occurrences and emergency centres;
- an outline of business continuity plans and strategies for the uninterrupted provision of essential services and products;
- availability and updates of public health emergency preparedness plans.(45)

However, the European Court of Auditors, in a 2016 report, observed challenges related to the enactment of Decision 1082/2013/EU, such as difficulties for some Member States in the reply to the surveys and such as technical flaws that affected data quality for specific queries. This led to reservations concerning the findings from the 2014 and 2017 progress reports.(46)

Furthermore, while there were acknowledgments of improvements made in the reporting process by early 2016, the Auditors couldn’t determine the effectiveness of the reported advancements. Concerns were raised about the ECDC's vaguely defined role in general readiness, which might hinder its future planning and response capabilities.

The onset of the COVID-19 pandemic shed light on the fragility of the European health safety framework, both at the Union's helm and within individual Member States. The WHO's Pan-European Commission on Health and Sustainable Development stressed the necessity for a consolidated monitoring system for health system preparedness, guided by a unified global entity for consistency and transparency.

Similarly, a 2021 report to the European Parliament emphasized that managing global pandemics requires collective effort, and the need of strengthening solidarity within the EU through Cooperation and coordination among Member States and all relevant stakeholders.(47)
The report by the European Parliament, however, focused on enhancing operational coordination at the European forefront and on reinforcing ECDC's capabilities, without discussing accountability measures for Member States.

On this basis, June 2022 saw the European Parliament provisionally concur on a novel EU legislation concerning serious cross-border health threats. This new law advocates for a robust crisis readiness framework, with the establishment of both EU and national health crisis and pandemic plans built on common frameworks to ensure coherent and shared response.

The Council and European Parliament also concurred on stress testing the EU's readiness and response plans, ensuring its periodic updates through the facilitation of the EU Commission, that will be also in charge of drafting public reports on health crisis management, with feedback from Member States.

November 2022 witnessed the ratification of Regulation 2022/2371: this law repealed Decision 1082/2013/EU, mandating Member States to update the Commission on their prevention, preparedness, and response strategies. The Commission, in turn, would inform the European Parliament and European Council triennially about progress in the above domains. The intention is for these plans to ensure readiness across pivotal societal sectors, maintaining essential services during crises.

In this direction, Article 1 of Regulation 2022/2371 fortified the Health Security Committee (HSC) and its pivotal role in readiness at both Union and national tiers. Moreover, Article 5 necessitates the formation of a Union health crisis and pandemic strategy, aligned with the WHO's emergency preparedness framework.

This EU initiative aims to support and synergize with national plans, fostering collaboration among Member States, the Commission, ECDC, and other vital EU entities.

Triennial reports from Member States based on common indicators (Article 7)

Under Article 7 of Regulation 2022/2371, Member States are mandated to report on their activities in prevention, preparedness, and response planning. From December 2023, every three years, they must update the Commission and related Union entities using agreed indicators.

This triennial report should encompass national and, if relevant, cross-border health sector standards for prevention and response planning, in line with the WHO's IHR.

It should also highlight health sector's interoperability with other crucial sectors during emergencies and provide an update, where necessary, on the elements of emergency prevention, preparedness, and response planning, including:

- governance, in terms of national and possibly regional policies, coordination among various administrative levels, and multi-sector collaboration;
- capacities, such as risk assessments, emergency preparedness priorities, early warnings, business continuity during crises, gender-sensitive health services, the effects of major cross-border health threats, and research to enhance readiness;
- resources for emergency preparedness and responses, medical supplies, logistics for medical countermeasure storage, and dedicated emergency personnel.

The triennial report also must cover the implementation of national prevention, preparedness and response plans related to threats specified in Article 2 of the Regulation, consultations and actions addressing identified preparedness gaps.

Subsequently, based on these triennial reports, the Commission, in collaboration with the ECDC and other Union agencies, will provide the HSC with a report encapsulating country-specific profiles to monitor and plan responses to national-level deficiencies.

ECDC Assessments of Member States' prevention, preparedness and response planning (Article 8)

Article 8 of Regulation 2022/2371 mandates the ECDC to evaluate the prevention, preparedness, and response planning efforts of Member States. Every three years, the ECDC should review how Member States implement their national prevention, preparedness, and response plans in alignment with the Union's plan as defined in Article 5. These evaluations will utilize a consistent set of indicators and will be carried out in collaboration with EU agencies with the aim of assessing national-level planning in light of the details presented in Article 7.
On these assessments the ECDC will be able to offer recommendations to both the Member States and the Commission. Following this, Member States are obligated to draft an action strategy addressing these suggestions, inclusive of proposed actions and significant milestones. This response should be delivered promptly, specifically within nine months after receiving the conclusions from the ECDC.

Triennial reports from the Commission on prevention, preparedness and response planning at the Union level (Article 9)

On the basis of the information provided by the Member States in accordance with Article 7 and the results of the assessment referred to in Article 8, the Commission has to prepare a report on the state of play and progress on prevention, preparedness and response planning at Union level.
Starting in December 2023 and every three years thereafter, this report is to be transmitted to the European Parliament and to the European Council.
The report is to include, where applicable, cross-border preparedness and response elements in neighbouring regions. Based on its report, the Commission may support the action of the Member States through the adoption of general recommendations on prevention, preparedness, and response planning.

Using the information given by the Member States in accordance with Article 7 and the findings from the assessment mentioned in Article 8, the Commission will compile a report detailing the progress and current state of prevention, preparedness, and response planning at the Union level.

Beginning in December 2023, and then every three years following, the report will be sent to both the European Parliament and the European Council.
The report will encompass cross-border preparedness and response activities in adjacent regions when relevant, and on its findings, the Commission might propose general recommendations to aid the Member States' actions concerning prevention, preparedness, and response planning.

Revised ECDC mandate

Separate legislation enacted in November 2022 (Regulation 2022/2370), empowers ECDC to monitor the capacity of Member States' health systems to detect, prevent, respond to, and recover from outbreaks of communicable diseases, identify gaps, and provide science-based recommendations for the strengthening of health systems. This monitoring is intended to be based on agreed indicators and conducted in close cooperation with Member States. Towards this end, ECDC is intended to organize visits to Member States to provide additional support for prevention, preparedness, and response planning activities.

The revised mandate also tasks ECDC with developing guidance and support organizing exercises, stress tests, in-action and after-action reviews, and support and complement Member States in those activities, and organize additional actions to address gaps identified in preparedness capacity and capability.

Implications for measuring and assessing emergency preparedness and response capacities and capabilities

From a measurement science perspective, triennial reports described in Article 7 are designed to ensure Member States' accountability to both the Union and other Member States, aligning with the requirements under the IHR and additional EU areas of intersectoral collaboration, such as antimicrobial resistance and medical countermeasures planning.

This is reflected in the report's structure, based on a universally agreed set of indicators, that should allow comparisons among Member States, track progress, and facilitate the creation of an EU-wide report. While Member States self-report via the Article 7 template, they retain significant autonomy in their health system management.

Conversely, the Article 8 assessments, building on the foundation of Article 7 reports and other sources, aim for systems improvement and resource allocation. These assessments, coupled with Member State visits as outlined in the revised ECDC mandate, foster a dialogue between the ECDC and the Member States with the goal of developing specific critical areas.
The Article 8 assessments, being inherently qualitative, pinpoint each Member State's individual strengths and areas of improvement, demanding a collaborative approach.

Objectives

The aim of the current PhD thesis is to study and upgrade conceptual frameworks of PHEP in response to pandemic emergencies and identify assessment models relating to the organization of care pathways, with a specific focus on the hospital setting and on the integration with primary care systems related to the rearrangements induced by the COVID-19 pandemic.

In particular, the work will represent a summary of the collaborative effort that ECDC engaged with researchers from the Department of Biomedical and Neuromotor Sciences of the University of Bologna, the Harvard T.H. Chan School of Public Health, and the Georgetown University to review documents and guidance on how to monitor and assess PHEP planning and effective response in case of communicable disease events in the EU, coherently with the evolution of the legislative context.

The work will be structured into two sections, each referring to specific research activities:

- section 1 will provide an overview of the outcomes published in the report "The EU experience in the first phase of COVID-19: implications for measuring preparedness";(48)
- section 2 will provide a summary of key findings on the development of a monitoring and evaluation methodology for PHEP.

Each section will include an overview of the methodological approaches, main results, and proposed implication for practice.

Building on both, the final outcomes of the current PhD thesis will consist in two papers that will review the current version of the ECDC Logic Model and summarize the major findings in the area of healthcare coordination.

SECTION 1 - THE EU EXPERIENCE IN THE FIRST PHASE OF COVID-19: IMPLICATIONS FOR MEASURING PREPAREDNESS

In light of the challenges faced during the COVID-19 pandemic, Decision 1082/2013/EU went under review, with the aim of strengthening the EU and Member States' collective ability to combat communicable disease threats in the future, testing their potential responses.

While small-scale disease outbreaks offer insights into PHEP systems, they do not fully test the wide range of capabilities required for a global pandemic. As a result, most preparedness metrics concentrate on organizational capacities. However, measuring capacities is problematic since there's limited evidence connecting them to response capabilities and desired outcomes.(49)
Hence, current preparedness metrics rely on professional judgment based on standard public health practices and past emergencies.
In contrast, with its significant global impact, the COVID-19 pandemic provided a unique opportunity to observe a comprehensive public health emergency response and assess the preparedness capacities and capabilities of EU Member States in action.

Because the same pathogen affected every country globally and in Europe, comparative analysis could establish the relationship between capacities, capabilities, and objectives.
However, comparative analyses must consider differences between countries, such as government structures, healthcare systems, priorities, timing and circumstances of pathogen arrival, population demographics, socio-economic factors, and political dynamics.
To address these challenges, it may be more effective to focus on capabilities rather than capacities. For example, while every country needed to conduct testing and surveillance, different systems and methods were used based on governmental structures, existing capacities, and activation of pandemic preparedness plans were used.
The pandemic not only allowed observation of capabilities individually but also demonstrated their interaction in achieving a rapid, comprehensive, and sustainable response. For instance, testing facilitated accurate surveillance, which, in turn, informed risk assessment and communication.
The observed capacity gaps during the pandemic offer valuable insights into the priorities for future preparedness metrics. For instance, experiences with testing and surveillance highlight the need to measure not just the existence of testing and reporting capacities for common notifiable diseases but

also the adaptability of these systems for novel pathogens and their ability to scale up in response to surges in cases.

The analysis conducted with the ECDC after the first phase of the COVID-19 pandemic aimed to capitalize on this experience by identifying challenges faced and successful responses, with a focus on informing future outbreak preparedness efforts in EU Member States.

The objective was not to evaluate specific Member States' responses but to use their experiences to identify essential preparedness capacities and capabilities gaps for inclusion in preparedness assessment tools.

Overall, three sets of capabilities, as described in the ECDC Logic Model were particularly stressed during the initial phase of the pandemic before vaccination programs began in December 2020: detection and assessment, health services, and emergency risk communication.

Methodological approach

To identify challenges encountered during the management of COVID-19 and successful responses, a research team, under the ECDC guidance, undertook a specific methodological approach that followed the following steps:

- five EU Member States (Croatia, Finland, Germany, Italy, and Spain) were selected to showcase different national organizational structures and responses to the pandemic; factors such as the research team's familiarity with the countries, language abilities, and the countries' willingness to participate were considered;
- key areas of analysis were identified within the capabilities domains of the ECDC Logic Model (testing and surveillance, healthcare sector coordination and emergency risk communication); the analysis primarily covered the first six months of 2020 and the subsequent steps taken to address identified gaps, excluding the period after the initiation of vaccination programs in December 2020;
- rapid literature reviews, pandemic preparedness plans, reports, and other relevant documents from the five countries were examined to create interview guides for each area of inquiry;
- interviews were conducted in collaboration with ECDC National Focal Points (NFPs) for Preparedness and Response in the five selected countries; these interviews, conducted with the Pawson and Tilley approach, included discussions with NFPs and other recommended experts;

- preparedness measurement issues in each area were analysed separately, drawing from documentary analysis, interviews with country representatives, and additional literature identified during rapid literature reviews; the analysis summarized the required capabilities during a pandemic and steps for preparation for future public health emergencies and contributed to an improved PHEP measurement framework, with preliminary results discussed in virtual meetings with ECDC NFPs for Preparedness and Response;
- implications of the findings from the three substantive summaries on measuring public health emergency preparedness were discussed, and comparisons were made with well-established preparedness assessment tools, including the ECDC Health Emergency Preparedness Self-assessment (HEPSA) tool, the WHO Joint External Evaluation (JEE) tool, and the Global Health Security Index (GHSI).

The following paragraphs summarize the results of in-depth analyses of the findings regarding which aspects of PHEP systems should be measured in the future, with a main focus on the healthcare section coordination area.

Healthcare sector coordination

Dealing with a public health emergency, especially a large-scale one, requires the coordination of a multiplicity of actors. Following the ECDC Preparedness Logic Model, four key capabilities in the context of the health services domain which healthcare organizations need to develop in order to tackle large-scale health emergencies were identified during the pandemic.

The first three capabilities are already represented in the Logic Model: management of medical countermeasures, supplies and equipment, medical surge, and hospital infection-control practices (this one is part of the domain “Policy development, adaptation, and implementation”).

In addition, a new capability named coordination of population-based medicine was proposed. This capability captures the COVID-19 experience in EU Member States more accurately than the current Logic Model’s preventive services, integrating the concept with that of population-based medicine, intended as health services, mainly primary care services, provided in out of hospital settings.

The following paragraphs 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.

Management of medical countermeasures, supplies and equipment

In the ECDC Logic Model, this capability is defined as the "ability to procure and distribute countermeasures, supplies and equipment, including personal protective equipment (PPE), during an incident."
Equipping emergency responders with the right tools is essential for dealing with any type of crisis. In the event of an outbreak, not only health care personnel but also other emergency responders, infected individuals, and generally all potentially at-risk individuals should have the appropriate personal protective equipment (PPE), of adequate quality and quantity. Health care facilities must have available the devices, drugs, vaccines, and equipment needed to cope with the early stages of the pandemic. Laboratories must have all supplies necessary to respond to a sudden increase in testing activity.

Since emergency equipment and supplies must be readily distributed to responders, it is prudent to have a stockpile set aside in advance. The usefulness of stock comes from the fact that the material stored in the warehouse is immediately available and usable: it saves time compared to placing an order and waiting for it to be delivered. To this it is added that in situations of crisis and global alarms, some supplies can suddenly become rare goods: they can turn out not to be available, can increase of it sensitively the price, could be delivered in times unusually much long. These stocks must be in good condition and - regardless of the logistical solution adopted, whether centralized or decentralized - must be able to be readily distributed to all operators and facilities involved in emergency responses.

To the extent that supplies prove insufficient, the emergency response system must be able to ensure the procuring and timely, continuous, and widespread distribution of supplies and equipment. If emergency supplies risk being unavailable on the market (or otherwise available but at high cost, or with excessively long lead times), national governments may decide to produce these materials themselves.
During COVID-19 pandemic, the overreliance on a few countries for production, competition among countries and supply chain disruptions have determined supply shortages globally.(50)

In Italy, as in many countries worldwide, the need to ensure adequate supplies (such as PPE, laboratory kits, respiratory support devices) was among the main critical issues early during the

COVID-19 pandemic, as reported in "Elementi di preparazione e risposta a COVID-19 nella stagione autunno-invernale".

During the emergency, a series of derogations have been introduced to Public Procurement Code (Legislative Decree No. 50/2016) in order to speed up the public procurement procedures for drugs, medical devices and personal protective equipment by the state administration and the Italian Civil Protection Department. Indeed, to coordinate the response to the crisis, including supporting the Italian regions with the procurement of the necessary supplies, the Italian Civil Protection Department (CPD) was in charge. It also had the task of monitoring and controlling the expenditure by implementing bodies, that contracted PPE that was delivered directly to the Civil Protection operations centre in Rome.

Notably, during the first wave of the pandemic, surgical masks were also produced by several companies in the fashion sector and companies in the personal hygiene sector and several businesses changed their production.(51)

At the beginning of the COVID-19 pandemic, PPE both for private use and for the healthcare sector was in short supply also in Germany, with a critical issue regarding overpriced items.[1]

A clear division of responsibilities often lacked, considering the German federated and self-governing system in the healthcare sector.(52) In this sense, health procurement was generally decentralized, although there has been an increasing centralization of the public one. Indeed, the Federal Ministry of Health pushed for increased centralization, ordering aggregated procurement of equipment needed for all doctor's offices and clinics.

In Spain, the Ministry of Health was in charge of monitoring stockpile and managing control measures.[2] Supplies of PPE in health facilities have been a concern in all regions, with a particular shortage of face masks caused by early panic buying; the shortages have encouraged profiteering. As a response, the central government centralized purchasing and introduced price controls on medicines requiring companies producing relevant equipment to inform the central government of their stocks.(53) Notably, on 26th of March, the Spanish Government announced a second purchase of masks for subsequent distribution by the Ministry of Transport, Mobility and Urban Agenda for the transport sector.(51)

[1] Interview with Germany, September 21, 2021
[2] Interview with Spain September 29, 2021

Finland, contrary to what has been observed in other countries that struggled to keep a steady supply of PPE, never experienced significant shortages.[3] Additionally, Finland was prepared for the increasing demand for medical supplies due to a stockpile gathered during the Cold War era and, a crucial element in the country's response to COVID-19.(54) According to the mandatory reserve supplies of medicine, a legislation from the time of cold war, companies have to stock medicines.[4] Indeed, the country largely met needs for medical supplies relying on the stock of the National Emergency Supply Agency (NESA) that, in late March 2020, opened its warehouses for the first time since the Second World War.(51) As observed in other countries, main issues were related to logistics, particularly to sharing and transport of PPE from one hospital to another[3]. As regards legislation, no changes to Finnish law have been implemented, while existing processes for emergency procurement has been emphasized.

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

- stockpile products, equipment and drugs considered essential to deal with a public health emergency;
- maintain multiple storage sites distributed throughout the territory;
- identify those responsible for procurement in emergency conditions;
- keep several purchasing channels open for redundancy;

Additionally, a key aspect that should be further considered, is the coordination between States in case of international joint procurements. During the COVID-19 pandemic, it emerged as a crucial strategy to address global shortages and ensure equitable access across nations.
By pooling resources and demand, countries could leverage their collective buying power to secure larger volumes of PPE at more stable prices, avoiding competition that drove costs to prohibitive levels. This cooperative approach could facilitate the distribution of PPE to frontline workers and vulnerable regions, promoting a more coordinated response to the public health crisis.
The shared responsibility in joint procurement emphasised global unity in facing pandemics, underlining that the health security of one nation is intrinsically linked to the health security of all.
To address this issue, the procurement and stockpiling of medical countermeasures (MCMs) were clearly defined as core areas of work within HERA's mandate.

[3] Interview with Finland October 6, 2021
[4] Interview with Finland, October 8, 2021

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."

To achieve this goal, health systems must be designed to be flexible and scalable, meaning they must be able to quickly scale up or down, as needed and without excessive cost, the volume of certain activities. In the specific case of an epidemic surge, the healthcare response system must be able to rapidly increase the number of patients admitted, the volume of diagnostic and therapeutic activities provided, surveillance activities and contact tracing on the territory.

To rapidly increase the volume of activities provided, it is necessary to have adequate resources, what in the ECDC Logic Model are defined as capacities (i.e., the infrastructure, procedures, and trained personnel on which healthcare facilities can rely). In the face of a medical surge, the risk is that hospitals do not have enough beds or space to admit and treat all patients. There is a risk that there are not enough specialized staff. There may be a shortage of machines, devices, medications to treat all patients simultaneously.

According to James Thompson, to manage peak demand, organizations can employ four strategies: buffering, smoothing, forecasting, and rationing.(55) These strategies can be combined with each other. Buffering means setting aside resources in excess of normal requirements. These extra resources constitute "safety valves", which can be activated and used under conditions of emergency or organizational stress. The design of health care systems must - in other words - be guided by the principle of redundancy.(56)

A second strategy is smoothing: in the case of a pandemic, smoothing can be achieved through a filtering action on the part of population-based medicine, so as to avoid patients going to hospital who could be treated more adequately at home or in outpatient community facilities. This, as well as the adoption of preventive and restraining measures, can have the effect of reducing 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 reorganize, to schedule staff shifts, to

stockpile, etc.) can be facilitated by the use of computer tools and mathematical and statistical models. The fourth and final strategy is rationing. It is usually the strategy to be implemented when the previous ones have not had the desired effects. Rationing corresponds, very concretely, to the priority criteria according to which patients are treated. Since it is not possible to take care of all applicants simultaneously, it is necessary to decide who to treat first and who later. Rationing criteria are typically adopted when designing vaccination campaigns. During COVID-19, individual countries applied these four strategies at different stages of the pandemic, in different ways, often combining them.

Another final element should be considered: since medical surge usually affects some hospital departments and not others, staff from less affected departments may be called upon to support the departments that are most under pressure. Highly reliable healthcare organizations should avoid such reduction of resources over time. In fact, it is important to ensure that the attention given to emergencies does not slow down or disrupt the day-to-day operations of other departments in the hospital.

To achieve this, it may be useful to design hospital structures according to the principle of modularity: the system's components must be separate, and combinable when necessary.

The malfunction of one organizational component should not extend to other parts and affect the entire system.

From March 2020, hospitals in the North of Italy reported system saturation, due to the high level of patients loads requiring intensive care. The shortage of hospital beds and ventilators as well shortages of personnel at all levels represented a concrete threat. In order support COVID-19 patients care, health staff moved from other services and disciplines and civil medical volunteers and other health care workers started to operate in the most affected regions.[5]

Moreover, civil medical volunteers and other healthcare workers started to operate in the most affected regions. 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.

Many hospitals had been converted into COVID-19 hospitals and new ones were built to increase the capacity of the system and provide care for those in need. As a result, at the beginning of April 2020, the number of intensive care beds almost doubled, and quadrupled in infection and respiratory disease departments.(57)

[5] Interview with Italy, October 6, 2021

The increase in hospital beds implemented during the emergency was subsequently consolidated by the decree law 34/2020, converted into Law 77/2020; particularly, the Art. 2 of the decree provided indications on hospital reorganization plans, aimed at making structural changes throughout the national territory, strengthening the equipment of intensive and sub-intensive care beds.
Drawing from the experience of the first wave, some elements have been identified that had to be checked to strengthen the state of preparation of health services at the regional level, such as the availability of suitable beds in ordinary hospitalization and in intensive and sub-intensive therapy dedicated to COVID-19 patients and the availability of trained and continuously updated health personnel, who can be reconverted to carry out assistance activities in the different settings in the event of an increase in the number of cases or who can support the prevention departments in carrying out diagnostic assessment, isolation, contact functions tracing, quarantine.(58)

In Germany, as observed in many other countries, elective surgery was stopped, and screening and medical treatments were postponed facing the increasing demand for COVID-19.(59)
Hospitals responded themselves or were forced by the federal regulation to care only for COVID-19 patients. Particularly, to manage the high load of patients, crisis team meetings were organized daily, while transfers of patients between federal states were occasional. Indeed, the country had already a high number of intensive care beds, even if the whole capacity could not be used completely because of shortages of nurses and intensive care units could not respond to non-COVID-19 patients as qualified staff able to respond to severally ill patients was pooled together within hospitals. The persistent modernization 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 than any other comparable country in Europe.(60)
The Federal Ministry of Health suggested hospitals to recruit more staff and health workforce strategies, that largely varied across German states, were put in place to strengthen and expand the workforce. The main efforts were concentrated on expanding health workforce capacities, while limited efforts were put on skill-mix and task-shifting. Examples of these strategies include covering extra working hours, the recruitment of retirees, special recruitment procedures for nurses and doctors. Additional medical and nursing students were recruited and allowed to perform supervised work in different COVID-19 response capacities.[6]

In Spain, at the beginning of the pandemic, health facilities in the worst affected regions struggled because of inadequate intensive care capacity and insufficient number of ventilators. In particular, Catalonia and Madrid cancelled non-emergency surgery and cleared beds where possible. A decree

allowed the regions to take over the management of private health services and military installations were used for public health purposes.(53) The decree also allowed the hiring of graduates without specialization, final year medical and nursing students, and extending contracts of medical residents to address the shortages of health staff.

In Finland, the coordination of the response to the COVID-19 pandemic was by area and daily meetings were held, especially at the beginning of pandemic, with the participation of the preparedness unit of the Ministry of Health, the five university hospitals and the head of THL.
The number of ICU beds and ward capacity varied across the country, but as of April 2020, the evaluation carried out on the ICU capacity outside the Helsinki-Uusimaa hospital district responsible for the capital region concluded that the potential estimated increase in beds capacity could be sufficient to meet the needs of COVID-19 patients.(61) Moreover, considering that Finnish hospital buildings were quite new, they could be flexible enough to accommodate the needs of the patients.[6]
Several evaluations were carried out also on personnel and stockpiles and a critical issue was represented by the lack of personnel, especially nurses, as observed in Germany therefore, nurses were retrained and transferred from operating room (OR) to the ICU.[7]

As for medical surge, the COVID-19 experience suggests, therefore, the following steps that countries might take in advance, and which could be the subject of preparedness measures:

- develop a healthcare system emergency plan;
- design hospital organizations to be flexible and scalable; if one organizational component is under pressure or out of order, another must be able to replace it;
- design hospital facilities with redundancy, building emergency reserves (buffers) in advance such as more beds, staff and equipment than strictly necessary under normal conditions;
- train 'multi-purpose' health personnel who can be used in different departments according to need;
- 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).

[6] Interview with Finland, October 6, 2021

Hospital infection control practices

In the ECDC Logic Model, this capability is defined as the "authority and practical ability to adapt existing (or develop new, if necessary) policies and guidance to both prevent the spread of infection in healthcare and related settings and for treating affected individuals, including crisis standards of care."

In the event of a pandemic, it is critical that hospital facilities are able to keep the flow of contagious patients separate from that of non-contagious subjects. Infectious individuals (confirmed, suspected, or possible cases of contagion) must be isolated, in order to avoid hospitals becoming vehicles and "multipliers" of contagion themselves.

This objective can be achieved either by selecting specific facilities to which all contagious individuals should be directed, or by identifying - within the individual hospital facility - the units dedicated to the diagnosis and treatment of infectious subjects. It is incumbent on the management of healthcare facilities to adopt (and enforce) protocols that prescribe what precautions hospital staff must observe, and that ensure the safety of hospital personnel, patients, and visitors.

Implementation of effective infection prevention and control (IPC) measures is needed to support global capacity building to limit the transmission of coronavirus COVID-19 and mitigate its impact on health systems.

The COVID-19 pandemic has shown a high incidence of transmissibility of health care-associated infections and outbreaks affecting healthcare workers (HCWs) who are at the forefront of these crises, illustrating the importance of being prepared.(62)

In Italy, several indications were issued in order to prevent the spread of SARS-CoV-2 in different settings, including long term care facilities.

In Germany, indications on how to separate suspected COVID-19 cases, non-COVID-19 cases and COVID-19 cases were issued rapidly early during the pandemic.[7] Designated hospitals or wards were identified and dedicated to COVID-19 care, and in some hospitals two different emergency areas were prepared. This kind of separation proved to be much more difficult in the ambulatory sector; additionally, every practice set up its own rules and many of them were not accessible, while some of them required a test. In order to improve access, many consultations started video calls, and in summer 2020 the legislation was adapted to allow vie/phone call in order to claim reimbursement from health insurance funds.

[7] Interview with Germany, September 21, 2021

In Finland, hospital access for COVID-19 patients was limited, with the preference of treating people at home as much as possible.[8] With this aim, phone call controls were carried out. COVID-19 was treated as any other disease, with guidelines for all HCW and for the elderly in nursing homes that were treated there and not in hospitals.

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

- draw up infection control protocols for each hospital healthcare facility 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 (population-based medicine)

The ECDC Logic Model includes a "preventive services" capability, 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 on population-based medicine 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 in- and out-patient settings, both in the interest of the patients and to help avoid hospital overcrowding. This might be complicated, however, because in many countries, public health and primary providers do not belong to the same organization and cannot be coordinated hierarchically. Moreover, healthcare providers practicing outside the hospital are distributed throughout the territory, and thus more difficult to coordinate.

Coordinating care in this way demands that systems have certain capabilities to perform under the pressure of a health emergency. Population-based healthcare professionals must be able to make autonomous decisions to act promptly in the absence of instructions from the centre.

[8] Interview with Finland October 6, 2021

Starting from emergency plans, primary care professionals (such as general practitioners or primary care paediatricians) must identify the most effective solutions for treating patients at home; care must be integrated, and multidisciplinary teams must be involved. 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 (general practitioners and public health 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.
It has been suggested that in the territories where a community-cantered approach to health care was more developed, health services seemed to have performed better in responding to the pandemic.(63)

During the first wave of the pandemic, the Italian Government approved the introduction of the USCA (Special Continuity Assistance Units) to offer specialized treatment at home for COVID-19 patients without severe symptoms to prevent their arrival at hospitals in critical conditions.(57) Moreover, the Ministry of Health announced the recruitment of community nurses and social workers to provide integrated care on the territory.
Additional measures to strengthen the health services at the territorial level were included in the decree-law 34/2020, converted into Law 77/2020. Particularly, Art. 1 saw the adoption of regional plans to strengthen and reorganize the territorial assistance with the aim of ensuring early care to infected patients, their contacts and people in isolation, as well as to fragile, chronic and disabling patients, foreseeing the strengthening of the main functions of the territory involved in the diagnostic assessment, monitoring and surveillance system of the SARS-CoV-2 disease, and the strengthening of home care activities both for infected patients and for subjects suffering from chronic diseases, disabled, with mental disorders, with pathological addictions, non-self-sufficient, with the need for palliative care and pain therapy. The activation of regional operational centres was also envisaged to ensure the coordination of the territorial health and social and health activities implemented.
A monthly mechanism for comparing the resilience of welfare and territorial services has been established, coordinated by the Ministry of Health and implemented by the ISS, with regular production of updates for each region and video-conference meetings with regional representatives of the regional health systems with the aim to ensure continuous coordination for the definition of timely responses and to support a timely and collaborative decision-making process.(58)

In Germany,[9] ambulatory care worked with their own practices paid by health insurance funds, and on individual basis. During the pandemic, professional associations of the federal states provided guidance with information; the Chamber of doctors provided information and checked on the needs as well. Health insurance companies regulated payments and provided indications on how to organize a practice, specifically giving guidance on how to organize a workflow. Indeed, in the early stages, GP practices were not well prepared and, in order to obtain information, were highly active on informal digital networks involving their professional peer group. At the national level, guidance was issued by the Robert Koch Institut (RKI, National public health institute).(64)

In Finland, Hospital Districts are made for specialized care, nonetheless, they have a tight connection with primary care.[10] Considering the flow of information from the territory, municipalities provided information to Hospital Districts, that was subsequently sent to university hospitals. As for the social services, gathering information from 300 municipalities was more changeling, as they do not have a structure of hospital districts.

A web-based national Omaolo COVID-19 symptom self-assessment tool was launched in March 2020.(65) 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 specialized 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 owned by the municipalities and provides tertiary-level care which formed a coordination group for in-patient care. Capacity data was also shared via emails and 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.

[9] Interview with Germany, September 21, 2021
[10] Interview with Finland, October 8, 2021

The COVID-19 experience suggests, therefore, the following steps that countries might take in advance, and which could be the subject of preparedness measures:

- prepare emergency plans that identify tasks, responsibilities and procedures to be implemented in a health emergency;
- health personnel working in the territory must have their own stock of PPE and all the tools necessary to implement these emergency plans;
- set up plans, protocols and telemedicine tools to treat patients at home;
- train territorial healthcare professionals to coordinate and communicate with each other;
- identify and operationalize 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.

Testing and surveillance

During the initial phase of COVID-19 in Europe, the detection and assessment domain within the ECDC PHEP Logic Model emphasized two key capabilities areas: laboratory analysis and surveillance and epidemiological monitoring. A third area, related to risk characterization was also relevant and analysed.(66)

Laboratory Analysis

In the ECDC PHEP Logic Model, "laboratory analysis" is defined as the technical proficiency required to identify possibly novel pathogens, monitor antimicrobial resistance, and efficiently handle a large volume of diagnostic samples.

The primary insight gained from literature reviews and discussions with public health experts in five countries is that the ability to conduct large-scale testing emerged as a critical capability during the early pandemic phase in EU Member States.

The inability to perform tests at a sufficient scale and obtain swift results had significant implications for clinical decision-making.

Moreover, the inability to expand testing operations also posed challenges for various aspects of public health operations, such as epidemiological investigations, contact tracing, situational awareness (e.g., determining when movement restrictions could be lifted), and risk assessment and characterization.

In response to the COVID-19 pandemic, certain capabilities became crucial for effective management. This included an emphasis on 'laboratory analysis' and 'surveillance and epidemiological monitoring,' with the Veneto region of Italy leading the way in early contact tracing and testing scale-up. Similarly, Germany, Finland, and Spain also demonstrated their preparedness in diverse ways.

Italy established a network of 31 laboratories for SARS-CoV-2 testing, while Germany quickly developed specific PCR tests and had a well-equipped laboratory infrastructure. In Finland, PCR testing was swiftly implemented with the help of established infrastructure and regulatory structures. Spain, on the other hand, faced initial challenges due to limited testing capacity and coordination issues among public and private laboratories.

These experiences highlighted the significance of “laboratory analysis” capability, especially the ability to operate at scale and promptly report results, the value of testing in various public health functions, such as surveillance, situational awareness, and risk assessment.

However, existing preparedness metrics like the HEPSA tool did not adequately cover laboratory capacities and capabilities, while the JEE tool had some indicators related to laboratory systems. The EU Laboratory Capability Monitoring System (EULabCap) offered detailed indicators for diagnostic testing, reference laboratories, and epidemic response support but needed updating.

In conclusion, the COVID-19 response underscored the importance of laboratory capabilities, necessitating a re-evaluation of preparedness metrics to better assess and improve readiness for future health emergencies.
The existing metrics do not consider the ability of a system to scale up during a pandemic, which is a crucial aspect of preparedness.
While the complexity of sub-national laboratory networks is indirectly addressed in assessment frameworks like JEE and EULabCap, it is not explicitly detailed.

Measuring the capacity to scale up during an emergency is challenging during peacetime. Proposed EU legislation on health emergency preparedness and response suggests using 'stress tests' to evaluate how a system would perform in such situations. Additionally, after-action reports can provide valuable insights.

Surveillance and epidemiological monitoring

In the ECDC Logic Model, the "surveillance and epidemiological monitoring" capability encompasses indicator-based and event-based surveillance, including case reporting and active surveillance for outbreak identification, characterization of affected population groups, monitoring disease trends, and assessing control strategy impact.

Reviewing literature and consulting with public health experts from five countries reveals that providing national surveillance data during the initial months of the COVID-19 pandemic posed dual challenges: modifying existing infectious disease reporting systems to include a new "notifiable disease" and adapting surveillance systems on an *ad hoc* basis to address unmet needs such as syndromic and hospital-based surveillance.

These challenges were, in part, attributed to the hierarchical structure of national public health systems. These systems typically included national public health authorities, reference laboratories, and sub-national authorities, each with varying organizational structures and responsibilities.
Primary care physicians and hospital providers, responsible for generating case reports, were sometimes outside the public health surveillance system's jurisdiction and overseen by separate agencies.
Adapting infectious disease surveillance systems required extensive communication and coordination among multiple entities at different hierarchical levels, including public and private sector and legislative changes were often necessary to facilitate system modifications.

In Italy, the first European country to document and report the COVID-19 outbreak, guidance on case notifications and event-based surveillance was provided to regions by the Italian Ministry of Health in January 2020. An integrated surveillance system was later implemented, combining epidemiological, case-based, and aggregated data sources, integrating them with the National Epidemic Intelligence Network. The legal endorsement of the EI Network was achieved in June 2021 through the implementation of the influenza pandemic plan.

In January 2020, the Spanish Ministry of Health and Autonomous Communities developed a protocol for early COVID-19 case detection. Initially, samples were analysed at the national reference laboratory and regional hospitals and laboratories as capacity grew. Despite initial challenges due to diverse data systems among Autonomous Communities, improvements were made in May 2020,

enhancing the completeness and quality of case notifications. Several information systems were also developed, including hospital occupancy, outbreak surveillance, and laboratory surveillance.

In Croatia, hospitals were initially tasked with testing and reporting positive cases to public health institutes within their respective counties during the first pandemic wave. A national database was later developed for surveillance purposes.

Risk characterization

The ECDC Logic Model defines risk characterization in the context of communicable diseases as the process of identifying key aspects of a pathogen and its epidemiological characteristics. This includes factors like the pathogen's origin, modes of transmission, risk groups, infectiousness levels, virulence, and available control strategies.
In Germany, the Robert Koch Institute (RKI) played a vital role in characterizing and analysing COVID-19 risks: it published risk assessments, response plans, and daily surveillance reports, aiding in informed decision-making for the government, local health authorities, and the public.

In Vo', Italy, nasopharyngeal swabbing revealed a high number of asymptomatic individuals with COVID-19, explaining the virus's unique spread. Italy established a monitoring system to assess regional public health systems' resilience and risk levels, ensuring data accuracy.
The Italian influenza pandemic preparedness plan established a network of public health representatives to assess risks and potential impacts, with a focus on genetic sequencing of new respiratory viruses and in June 2021, the Italian Ministry of Health launched the Epidemic Intelligence Network for early risk identification.(67)

While the ECDC model focuses on risk characterization, its description results incomplete, since it encompasses two other capabilities ("incident recognition" and "epidemiological investigation") which are related to epidemic intelligence that should be specifically included in the domain of detection and assessment capability.

The COVID-19 experience stressed the need for a comprehensive approach, integrating epidemic intelligence into action plans, considering regional variations in disease impact and social consequences.(66)

Emergency Risk Communication

Responding effectively to large-scale emergencies necessitates continuous and timely communication. This involves interaction not only with the public but also with various organizations within the public health system.

Emergency risk communication (ERC) is defined as the real-time exchange of information, advice, and opinions between experts, officials, and individuals facing threats to their survival, health, economic stability, or social well-being.

The ECDC Logic Model includes four ERC capabilities: address communication inequalities, use dynamic listening and manage rumours, communicate risk in an accurate, transparent, and timely manner, and foster and maintain trust.

It's essential to note that these capabilities differ from another set related to coordination and communication within the public health emergency preparedness system, which were not included in this analysis.

Globally, all four capabilities faced challenges during the pandemic. Furthermore, every country encountered difficulties in managing the unprecedented influx of information. To include this important aspect, the capabilities listed in the original ECDC model are revised and expanded into five capabilities: communicate risk in a timely and transparent manner, foster and maintain trust with the media and the public, communicate risk in a clear, consistent, and empathetic manner, identify and address communication inequalities and 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.(68)

<u>Communicate risk in a timely and transparent manner</u>

Drawing from scientific literature and interviews conducted for this analysis, the COVID-19 experience reaffirmed the critical importance of timeliness and transparency in emergency preparedness. The timely response and transparent actions of responsible agencies are pivotal for building trust. Delayed actions can erode public trust in government and public health institutes, undermining the overall effectiveness of the response and crisis management.

To achieve timeliness and transparency, experts emphasized the need to involve risk communicators in preparedness and response efforts within multidisciplinary teams. Adequate resources should be

allocated to this vital capability. In the pursuit of transparency, several governments adopted practices such as creating open data dashboards and adopting open information-sharing approaches. This not only benefited their own nation but also contributed to international efforts, as epidemiological data shared by one country aided others in planning for similar situations.

Effective ERC was described as a collaborative endeavour, involving coordination among government agencies and external partners like media and social media companies. Building these partnerships and collaborations before an emergency is crucial and should be part of preparedness measurement initiatives.

In Spain, during the initial phase of the pandemic, government transparency with the media was improved by altering procedures for journalists' questions at press conferences. Spain initially adopted the 'one spokesperson' model but later incorporated various expert perspectives, resulting in multiple messages and a challenge in maintaining a unified voice.

In Finland, to enhance transparency with the media, the government established a dedicated phone line for journalists to ask questions and provided an open-access database with daily situation reports. Similar approaches were recognized as valuable by experts in other countries.

The Italian Ministry of Health promptly established a thematic website dedicated to the new coronavirus on the institutional portal. This site is continuously updated with evidence-based information for citizens, healthcare professionals, travellers, workers, and businesses. Citizen-response services operate 24/7 with trained operators and healthcare executives, while professionals involved in the response receive ongoing training to ensure service quality.

Foster and maintain trust with the media and the public

The COVID-19 pandemic, marked by prolonged public health measures and restrictions, posed a unique challenge in sustaining public attention and trust over time. In Germany, a significant decline in public interest in COVID-19 during the initial wave was observed, highlighting the difficulty of keeping people informed and aware of ongoing infection risks as the pandemic progressed.(69)

Furthermore, as the crisis unfolded, criticism of public authorities and trust in information sources became increasingly critical.(70) Distrust in government institutions, misconceptions about disease

prevalence, and feelings of vulnerability due to perceived lack of protection or prevention measures have led individuals to perceive a loss of personal sovereignty. In response, some have turned to unverified or exaggerated sources of information and resorted to irrational decision-making processes in an attempt to regain a sense of control over their actions and surroundings. This polarization within society carries the potential to impact both domestic and international security.

To nurture and sustain trust, timely communication is essential. A designated spokesperson or team should provide updates on both known and unknown aspects of the situation, acknowledging gaps in knowledge and signalling the possibility of decisions changing based on emerging evidence.

Communicate risk in a clear, consistent, and empathetic manner

This analysis emphasizes the need for synchronous communication across various channels, not just timeliness. To achieve this synchronicity, it is crucial to establish communication channels and procedures for sharing information with the public before emergencies, fostering coordination between national and sub-national agencies.

Furthermore, the analysis underscores the significance of identifying expert intermediaries who understand the technical language relevant to the target audience, such as trade organizations, industries, and commercial entities. Most governments have established mechanisms to respond to public and media inquiries, which should be integral to preparedness measurement efforts.

Additionally, recognizing individuals who possess cultural expertise within the population is essential. They can provide guidance on employing empathetic and culturally appropriate language that respects the perspectives and emotions of the audience the message is intended for.

Identify and address communication inequalities

Communication inequalities are prevalent, reflecting disparities in how different population segments access, comprehend, and respond to crisis information. To address these inequalities, a diverse array of communication channels should be utilized, and messages should be tailored to the literacy levels and socio-cultural backgrounds of the target audience.

Additionally, interviewees emphasized the significance of creating educational initiatives at both the citizen and media levels. These efforts, including outreach programs and community-based events like science fairs, foster a scientific culture among the public. These actions should be incorporated into the assessment of preparedness initiatives.

Infodemic management

All four capabilities mentioned above are associated with “infodemic management”, defined here as the management of excessive information, including both accurate and inaccurate data, during an epidemic. Effective infodemic management begins with the capacity to engage in social-listening activities, understanding public concerns and reactions to the information overload, misinformation, and disinformation, and assessing their potential impact on behaviour.
National experts, as part of their interviews, emphasized the importance of monitoring information dissemination across various media and social media platforms. They also stressed the need to develop mechanisms, such as chatbots, to enhance the government's ability to respond to public inquiries. However, interviewees also highlighted the importance of discerning which rumours might influence behaviour and warrant the development of counter-messaging strategies.
In summary, a strategic plan for infodemic management is a crucial element of preparedness activities and should be integrated into measurement efforts.

Measurement tools

An essential goal of this overview was to find of issues and solutions to enhance EU Member States' capacity to evaluate readiness for communicable diseases drawing insights from five countries' responses during the initial COVID-19 phase with the goal of the development of shared metrics and indicators.
The findings are intended to define and improve them, regardless of the specific quality management system a country’s PHEP system employs.

A high level of preparedness, informed by valid and reliable preparedness indicators, implies that an organization 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 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.
Existing measurement tools where compared (HEPSA, JEE, GHSI) for what (which capability areas) and how they assessed preparedness with key relevant findings:

- the COVID-19 outbreak necessitated EU states to rapidly devise and adapt PHEP systems and policies under pressure;
- current preparedness indicators rarely reflected a country's internal hierarchy impacting emergency responses or the essential coordination among healthcare sectors.
- indicators often neglected challenges in scaling up pandemic responses.

Overall, several gaps in tools like HEPSA and JEE were identified, mainly related to the fact that some indicators were incomplete because unable to address the ability of systems to scale up their capacity or to properly adapt and modify existing routine during the pandemic and that certain capabilities within the ECDC Logic Model, such as medical countermeasures or infodemic management were often missing or overlooked in current assessment tools.

Revision of the Logic Model

According to the domains explored, a redefinition of capabilities within the Logic Model is needed, especially for those related to the areas of detection and assessment, health services and emergency risk communication.
On the basis on the experience of the five selected countries, the examined documents and literature, and the interviews conducted in collaboration with ECDC National Focal Points (NFPs), the following modifications of response capabilities were proposed:

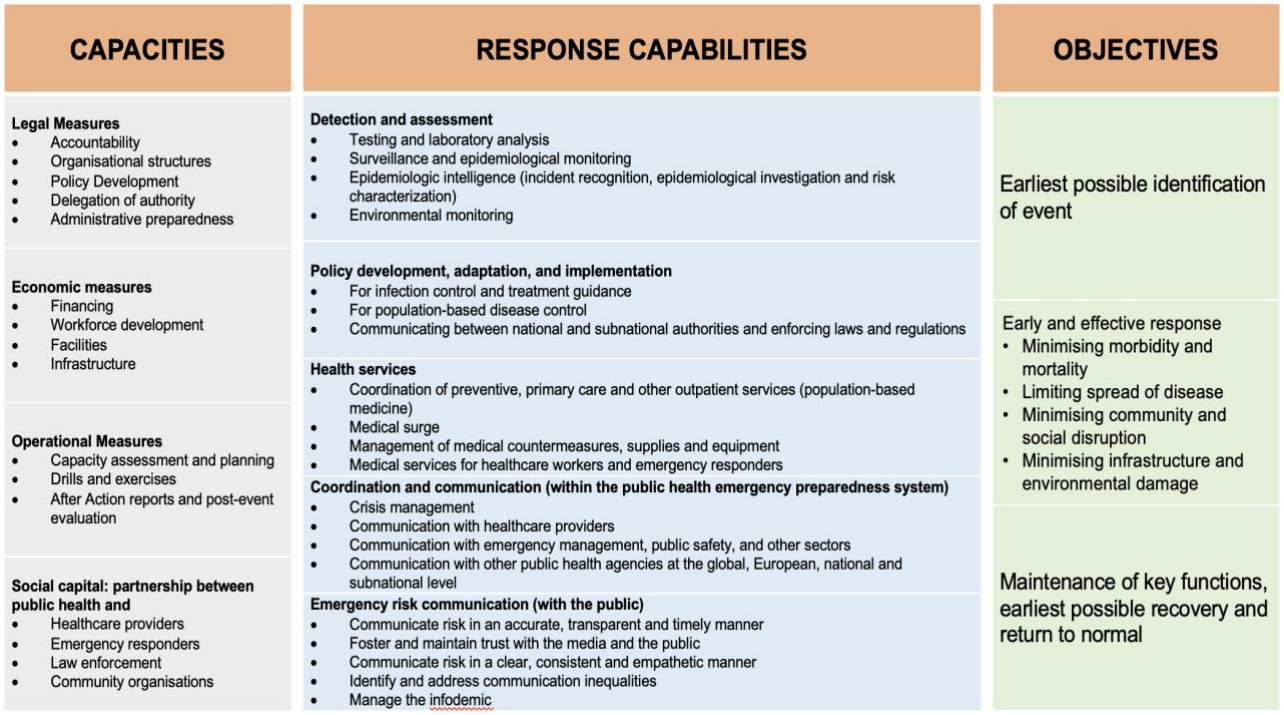
- in the detection and assessment area, “laboratory analysis” was integrated with “testing”, better represent their combined role; additionally, “incident recognition”, “epidemiological investigation” and “risk characterization” were included under the wider definition of “epidemiological intelligence;
- in the health services area, “preventive medicine” was replaced with the most specific “coordination of preventive, primary care and other outpatient services (population-based medicine)”
- in the emergency risk communication area, “address communication inequalities” was integrated with “identify”; “use dynamic listening and manage rumours” was replaced with “manage the infodemic”; “foster and maintain trust” was integrated with “with the media and then public”, clarifying the most important target of this process; the new capability “Communicate risk in a clear, consistent and empathetic manner” was added.

As the main objective remains the same and no specific elements emerged from the analyses, no structural modifications were proposed for the other domains of the Logic Model.

Nevertheless, given the considerations previously mentioned regarding the relationship between PHEP and resilience (that can be defined as the ability of a system to absorb shocks, maintain basic functions, and return to normal as soon as possible), some changes were proposed for the terms used in the "Objectives" section to better highlight some key elements of this concept.

Additional considerations might further modify the terminology, the order of capabilities and the aggregation used, but the elements introduced in this revision certainly serve as an important update of the current EU framework for PHEP.

Figure 3: Proposal for the revision of the ECDC Logic Model



SECTION 2 - METHODOLOGICAL INSIGHTS FOR MONITORING AND ASSESSMENT OF PUBLIC HEALTH EMERGENCY PREPAREDNESS

In order to support, enhance, and strengthen EU Member States and EU pre-accession and neighbouring countries in building PHEP strategies and practices based on sound measures of current preparedness capacities and capabilities, in the last few years ECDC aimed at the production of an updated report on elements and indicators for monitoring and assessing public health emergency preparedness planning among Member States.

An essential goal was to build on the experiences described in section 1 focused on the identification of preparedness capacities and capabilities that were essential in the response to COVID-19, and to define specific measurements and assessment methodologies coherent to the evolution mentioned in the introduction section of EU legislation according to regulation 2022/2371, especially in relation to article 7 and article 8, and regulation 2022/2370 amending the mandate of ECDC.(48)

Over the past two decades, there have been significant improvements in PHEP measurement, especially in the context of the new EU health security framework and the COVID-19 pandemic spotlighting the need for effective preparedness tools. Notably, the IHR mandates countries to annually report their ability to uphold core capacities and address potential global health threats using the SPAR tool.

Furthermore, the WHO introduced a Monitoring and Evaluation Framework (MEF) to foster transparency and shared responsibility among countries for global health security. This framework not only encompasses the obligatory State Party Self-Assessment Annual Reporting (SPAR) but also involves qualitative methods like voluntary simulations, after-action reports, and external evaluations.

However, the unique and multifaceted nature of public health crises, with their intricate interplay among diverse sectors and stakeholders, presents measurement challenges. Drawing from the lessons of COVID-19 and merging insights from various fields like epidemiology, statistics, industrial engineering, and case study methodologies, a refined “science of measurement” for PHEP is taking shape, as some authors clearly represented.(71)

The foundation of PHEP measurement should begin by understanding “why” it is important to measure, emphasizing goals like accountability, quality enhancement, and resource deployment and the answer to this foundational question helps in determining “what” and “how” to measure, as well as evaluating the effectiveness of these measurements.(72)

The current PHEP measurement terminology, developed in a piecemeal manner, lacks consistency, emphasizing the need for clear definitions. Many systems use “criteria and metrics”, reflecting overarching concepts of assessment and measurement. This language is notably present in the 2022 EU legislation on cross-border health threats, differentiating between Member States' triennial reports using standardized measures and their external assessments concerning national preparedness and response plans.

Central to these systems are metrics or indicators. They detail specific PHEP performance elements, ranging from observable behaviours to processes. Essentially, metrics serve as a standard language for describing and assessing performance.
These metrics rely on data, stemming from observed tasks outlined in surveys or checklists. This data mainly focuses either on capacities, like resources and personnel, or operational capabilities, such as the proficiency to execute plans. Performance can be gauged - and data generated - during drills, exercises, or real-time health crises, with evaluations either from participants or third-party observers. This results in either quantitative PHEP measures or more qualitative assessments.

Capacities spotlight the resources a public health system possesses, from infrastructure to trained staff. The daily operations of public health preparedness organizations, like planning or training, are geared towards enhancing this capacity. Conversely, capabilities spotlight the actual actions a system can take during emergencies, from surveillance to risk communication. Given that capabilities are underlying traits of the PHEP system, real-world emergencies are invaluable moments to evaluate them.

Why, what and how to measure

The specific aim of the measurement can be different. Considering some tools, subsequently described, the primary purpose of the WHO’s SPAR reports is to ensure country’s accountability for what is required under the International Health Regulations (IHR).

The JEE tool, on the other hand, is intended to improve the quality of countries preparedness systems by identifying gaps, as well as to mobilize resources (including from international donors) to fill those gaps.

A logic model, informed by research and professional insights, is essential in determining "what to measure". It outlines public health preparedness goals, objectives, and the activities aimed at building capabilities and capacities.

The ECDC's Logic Model, differentiating between capacities and capabilities, served this purpose. Originally developed in 2017, this model has been revised as mentioned in section 1 to better represent capabilities that were essential in the EU experience in the first phase of COVID-19, with the following areas being mainly affected by the changes: testing and surveillance/epidemiological intelligence, healthcare sector coordination, and emergency risk communication.

When determining measures, it's crucial to clearly define the necessary data elements and establish a consistent data collection method. In the realm of health services research, a distinction is made between broad concepts and their specific metrics. For instance, the proficiency of public health systems to detect outbreaks or communicate with at-risk populations can be represented in various ways. Effective performance metrics necessitate a systematic approach encompassing data collection, validation, and aggregation.

Metrics can either be quantitative, such as time taken for a task or vaccine stock, or qualitative, like an expert's evaluation of a health department's surveillance practices. While quantitative measures are perceived as more objective, their accuracy hinges on factors like evaluator training and the measurement system's execution. Biases, like misrepresenting time measurements, can be mitigated by involving third-party observers.

For the sake of accountability, it is vital that PHEP measures remain consistent, ensuring they are comparable across time frames, units, or against performance benchmarks. These definitions often encompass aspects such as the unit of measurement, duration, among others.
In comparative scenarios, qualitative evaluations might be converted into quantitative ones, such as a scale rating from 1 (insufficient response) to 5 (exceeding expectations). Proper standardization involves detailing each scale point, exemplified by tools like WHO's JEE.

When the emphasis leans more towards quality improvement in complex PHEP systems, qualitative assessments of system capabilities might prove more insightful than quantitative ones. Upholding the rigor of these assessments can be demanding. However, established social science methodologies offer valuable guidance.

Building on these premises, several researchers developed criteria to enhance the validity of qualitative assessments of PHEP underlining how in the healthcare sector measures are assessed in terms of their scientific performance – validity and reliability – as well as feasibility and utility.

These characteristics are equally relevant and important in measuring and assessing public health emergency preparedness, but there have been relatively few quantitative or other formal evaluations of PHEP measures.

Methodological approach

Based on previously established goals and a conceptual framework, an analysis was undertaken by reviewing documents from key European and international institutions concerning cross-border health threats and measurement tools for PHEP. The research was based on four main stages, as described below.

1. Identification of key relevant documents:
    - European Union – Regulation 2022/2371, the updated ECDC mandate, the template for reporting under Art. 4 of Decision 1082/2013/EU (as the reporting template for art 7 under the Regulation adopted in 2022 was not publicly available at the time of writing this methodology);
    - ECDC – PHEP core competencies, self-assessment tool (HEPSA), reports on lessons learned during the COVID-19 pandemic;
    - WHO – State Party Self-Assessment Annual Reporting (SPAR) and Joint External Evaluation (JEE) tools, and the Universal Health and Preparedness Review (UHPR);(73)(74),(75)
    - OECD – health system resilience assessment approach;(76)
    - EU/EEA Member States – reports on preparedness and response challenges identified during COVID-19 and action plans to enhance preparedness and responsibilities and capabilities.

    Additional literature, and inputs on the development of the methodology was provided by the network of ECDC national focal points (NFPs) for preparedness and response.

2. Analysis of EU legislative mandate and individual monitoring and assessment (M&A) approaches: the initial focus was on the EU's legislative mandate, specifically Article 7 and 8 of Regulation 2022/2371, and stress test references. Each M&A approach was further scrutinized based on the reasons, objectives, methods, and effectiveness of their operations.
3. General analysis of the selected M&A approaches: from the Regulation's requirements for measurement (Article 7 and 8), the research highlighted useful indicators from M&A tools for capacities and capabilities, identified measurement gaps, best practices recommended by existing M&A methods, and other insights.
4. Development of proposed M&A metrics, tools, and approaches: drawing from the articles 7 and 8, and from research results on measurement methodologies, proposals were made concerning potential new evaluation methods and indicators to be taken into account.

The main results, described in the following paragraphs, will focus specifically on general findings in methodological assessment approaches for two capabilities areas (testing and surveillance/epidemiological intelligence and healthcare sector coordination) and on key metrics, assessment tools and qualitative approaches for quality improvement coherent to the evolution of the legislative mandate for measuring and assessing public health emergency preparedness.

Surveillance and epidemic intelligence

Beyond the question of how to measure and assess preparedness, the COVID-19 pandemic also identified substantive weaknesses in the European health security framework. This recognition led to specific provision in Regulation 2022/2371, the establishment of the Health Emergency Preparedness and Response Authority (HERA) in 2021, as well as changes to the ECDC mandate.
For example, with a detailed report to the European Parliament, the EU highlighted challenges in obtaining uniform data, emphasizing the need for the EU to aid Member States in data collection and sharing during health crises.(47)

The receipt of comparable data should enable the ECDC to carry out surveillance of epidemiological data at European level which would ensure better preparedness. In particular, the report recommended that the Early Warning and Response System (EWRS), which is managed by the ECDC, should be updated with modern technology to ensure its interoperability with international, European, national, and regional alert systems regardless of the nature of the threat. In order to enhance the fight against

disinformation, the report also recommends that the ECDC should broaden its communication to European citizens by establishing a portal to share verified information.
A more recent summary identified the need for improved collection and analysis of data and evidence as one of four major lessons learned from the pandemic.(77)

Similarly, a report of the COVID-19 Committee of the Accademia Nazionale dei Lincei (Italian S20 Academies of Sciences) called for a far more comprehensive system for generating epidemic intelligence on pathogens of concern than represented in the WHO'S SPAR and JEE tools.
Much of this would be the responsibility of international organizations such as the WHO and ECDC. Some Member States have their own capacities and capabilities in this regard, but it is reasonable to expect that every Member State has some capacity to interact with and contribute to international efforts. The report also called for the capacity to generate information more effectively on what works in real time, in both clinical and public health settings. As with surveillance and epidemic intelligence, this requires a collaboration between international bodies and Member States.(78)

The Lancet Commission on lessons for the future from the COVID-19 pandemic concludes that strong public health systems should include strong surveillance and reporting systems as well as investments in research in behavioural and social sciences to develop and implement more effective interventions.(79)
The Lancet Commission recommends that each country determine and expand national pandemic preparedness plans to prevent and respond to newly emerging infectious diseases that should include improved surveillance and monitoring, international notifications, and cooperation within WHO regional groups.
According to this Commission, public health systems also require effective health communication strategies, active efforts to address public health disinformation on social media, and continuously updated evidence syntheses. Thus, national PHEP plans should include effective risk communication and active opposition to misinformation and disinformation.

Article 5 of Regulation 2022/2371 calls for the development of an EU prevention, preparedness and response plan to complement national plans and to promote effective synergies between the Member States, the European Commission, the ECDC and other relevant EU agencies or bodies, that must include provisions for:

1. the secure exchange of information between the European Commission, the Member States;

2. epidemiological surveillance and monitoring;
3. early warning and risk assessment, especially regarding cross-border interregional preparedness and response;
4. risk and crisis communication, including to health professionals and citizens;
5. health preparedness and response and multi-sectoral collaboration, following the One Health approach for zoonotic, food and waterborne diseases and relevant other diseases and related special health issues.

Similarly, the revised mandate tasks ECDC with providing timely epidemiological information and analysis of that information, epidemiological modelling, anticipation, and forecasting, and with providing timely relevant risk assessments and science-based recommendations, which set out options for the prevention and control of communicable diseases.
With the aim of improving the effectiveness of Union's epidemiological surveillance, the ECDC must continually enhance secure digital tools, integrating innovative technologies like artificial intelligence and computer simulation for data analysis, supporting Member States in creating comprehensive epidemiological surveillance systems. The updated mandate also emphasizes the rapidity of risk assessments while gathering all necessary information, aligning the Centre's actions with the 'One Health' approach, acknowledging the link between human, animal health, and the environment, especially since many outbreaks stem from zoonotic sources.

The 2022 ECDC report clarified that current preparedness strategies often don't capture the scaling challenges faced by countries during pandemics, specifically in lab testing and surveillance. National surveillance data provision proved problematic during the pandemic, especially when adapting existing disease reporting systems for a new "notifiable" disease and creating specific surveillance systems, such as for hospital capacity. The pandemic underlined the significance and intricacies of regional surveillance structures, the hurdles in updating current and crafting new surveillance systems, and their importance in epidemiological investigation.

Changes in the revised European health security regarding surveillance, data sharing, and epidemic intelligence are focused on the Union level, including the ECDC. However, every Member State must have some level of competence in these areas, and at a minimum must have the capacity to interact with ECDC and other countries and international organizations. Thus, from a measurement perspective, the implication of changes in surveillance, data sharing, and epidemic intelligence have implications for what to measure: Member States' own capacities and capabilities for surveillance

and epidemic intelligence, as well as their ability to communicate and interact with ECDC and internationally.

The SPAR and JEE tools currently include items related to specimen referral and transport, laboratory quality systems, laboratory testing capacity, event verification and investigation, an early warning surveillance function, and analysis and information sharing.

A far more comprehensive system for generating epidemic intelligence on pathogens of concern than represented in the SPAR and JEE tools, however, has been suggested together with the capacity to generate information more effectively on what works –in both clinical and public health settings– in real time.

Health sector coordination

As noted above, a report to the European Parliament in 2021 concluded that the COVID-19 crisis demonstrated that no country could fight a global pandemic alone. Cooperation and coordination between national health systems and a close and structured dialogue with all stakeholders are essential to ensure solidarity within the EU. The report further concluded that the priority should be to ensure 'health solidarity' by reducing health inequalities between and within Member States. Similarly, the Pan-European Commission on Health and Sustainable Development found that the pressures on the health system that have resulted from COVID-19 throw into sharp relief the failure in many countries to invest in hospitals, primary and social care with flexibility to respond to the crisis that so many had warned about for decades. Policies to increase the resilience of health system, the Commission recommends, should be cantered around the importance of the infrastructure of health systems, including the design of health facilities, the health workforce, and the relationship between health and social care.

Similarly, the already mentioned Lancet Commission report finds that strong public health systems should include strong relationships with local communities and community organizations and robust medical supply chains. In addition, the health-care system should include universal health coverage that is cantered around primary health care and ensures that patients have access to quality care for pandemic-related and non-pandemic-related health issues, including mental health. Community health workers and community-based organizations should be well trained and supported to effectively collaborate with institutions on public health emergency preparedness.(80)

Thus, every country needs to determine and expand national pandemic preparedness plans to prevent and respond to newly emerging infectious diseases that include robust health-commodity supply chains (e.g., personal protective equipment, diagnostics, therapeutics, and vaccines).

The European Observatory reports that during COVID-19 experience the importance of coordination between Public Health and Primary Care clearly emerged. Public Health plays a key role in reducing transmission of the pathogen through non-pharmaceutical interventions, Find-Test-Trace-Isolate-Support (FTTIS) operations, and vaccination campaigns.(81)
Primary care, on the other hand, is critical for maintaining routine public health services (e.g., routine vaccination, screening, check-ups), as well as treating mild COVID-19 cases. Indeed, in many countries COVID-19 patients were increasingly treated in outpatient settings.

The ECDC report published in 2022 highlighted that existing preparedness measures generally do not reflect a country's internal hierarchical structure of public health, healthcare, and other entities that influenced emergency responses, the required coordination among the different sections of the healthcare system, particularly hospital level and community-based medicine and that generally do not represent the challenges of scaling up a country's pandemic response.(48)

The preamble of Regulation 2022/2371 echoes these findings, concluding that the COVID-19 pandemic demonstrated that major diseases could put severe pressure on the capacities of healthcare systems. Disease outbreaks absorb an important part of health system capacities, and thus can have a negative impact on the provision of healthcare for patients with other communicable or non-communicable diseases, such as delay of or interruption to treatment for cancer patients and survivors and people with mental health issues.

Thus, while respecting the responsibilities of Member States for the definition of their health policy and for the organization and delivery of health services and medical care, the impact an important outbreak of a communicable disease can have on the continuity of healthcare and on the prevention and treatment of non-communicable diseases and comorbidities needs to be considered.

Consequently, in order to ensure the implementation of the Union prevention, preparedness and response plan, Article 5 of the regulation calls on the Commission to facilitate, in collaboration with Member States and, when applicable, with relevant Union agencies or bodies or with international

organizations, “stress tests,” simulation exercises and in-action and after-action reviews with Member States and update the plan as necessary.

In Article 7, the capacities to be included in national preparedness plans are expected to include “health and emergency services” and “the provision and continuity of healthcare services for other diseases and conditions during public health emergencies.” Resources include “essential supplies for health” as well as “logistics mechanisms, including for the storage of medical countermeasures; dedicated, trained and equipped human resources for emergencies.”

The Health Emergency Preparedness and Response Authority (HERA) – a directorate general of the European Commission – is considered as a key pillar of the European Health Union. The authority has to ensure enhanced coordination between Member States, structured cooperation with stakeholders and robust end-to-end solutions for availability and accessibility of medical countermeasures (MCMs).(82) To facilitate preparedness planning and health system coordination, HERA, together with the Member States, identifies on an annual basis three specific high impact health threats to ensure preparedness and response, in particular by addressing possible gaps in the availability and accessibility of MCMs and then by acting as a central purchasing body for Member States through different purchase mechanisms (wholesale procurement, joints procurement and grants).(83)

Despite these analyses about the importance of the health sector, Regulation 2022/2371 is somewhat ambiguous about the meaning of “health systems.” In some reports, the phrase seems to refer to the healthcare delivery system, i.e. hospitals and other facilities, physicians, and other professionals, etc. who provide healthcare to individuals. Elsewhere, “national health systems” seems to include governmental public health agencies as well.

Public health and health care systems operate at different level - national, regional, and local levels, with respect to different areas – and coordination of activities as well as communication among multiple public and private entities at all levels is a topical issue.
Particularly, the ability to coordinate efforts between levels (national, regional local, organizational) during a public health emergency also depends on the existence of specific communication channels and existence of data systems.

Coordination between Public Health and the healthcare delivery sector, especially Primary Health Care, is emerging more and more as relevant, not only to build a strong network among the different components of the healthcare sector and for a more integrated provision of routinary care, but also to counter a health emergency more effectively.

Regulation 2022/2371 defines "health system capacity" as the degree to which a health system maximizes its performance on the six health system core components or building blocks: service delivery, health workforce, health information systems, access to medical countermeasures, financing, and leadership and governance. This seems to refer more narrowly to the healthcare delivery sector, and not public health.

Both Regulation 2022/2371 and the revised ECDC mandate refer "to stress tests," but neither defines nor further explains the term. The revised mandate tasks ECDC with developing "exercises, stress tests, in-action and after-action reviews, and support and complement Member States in those activities, and to organize additional actions to address gaps identified in preparedness capacity and capability."
This suggests that the stress tests are to be part of ECDC's Article 8 assessments of Member States. Regulation 2022/2371, on the other hand, calls for stress tests both in Article 5, which is about the Union-level prevention, preparedness, and response plan and in Article 7.

Legislative requirements and expectations

Article 8 of Regulation 2022/2371 calls on the ECDC to assess the Member States' state of implementation of their national prevention, preparedness and response plans and their relationship with the Union prevention, preparedness, and response plan (Art. 5) in relation to the country reports required in Article 7. These assessments are intended to be carried out every three years and based on a set of agreed indicators. In addition, its revised mandate enables ECDC to organize visits to Member States to provide additional support for prevention, preparedness, and response planning activities.

Taken together, these two provisions create a very different set of expectations and requirements for measurement and assessment under Article 8 than under Article 7.

The purpose of Article 7, like its predecessor Article 4 of Decision 1082/2013/EU, is to ensure Member States' accountability to the Union and each other for what is required under the International Health Regulations (IHR), as well as additional EU expectations on interoperability of plans and intersectoral collaboration, measures to tackle antimicrobial resistance, plans for medical countermeasures, etc. The purpose of Article 8, on the other hand, is systems improvement and resource allocation.

Building on the Article 7 reports and other information, as well as the "visits" to Member States called for in the revised ECDC mandate, Article 8 assessments are intended to inform a dialog between ECDC and the Member States. Their goal is to focus ECDC's efforts to help the Member States address areas that need to be developed. Labelled "audits" in the draft regulation introduced in 2020, the term was changed to "assessments" on the grounds that the Member States have competence for health management issues, so the Union does not have the legal authority for audits.

Intended for systems improvement and resource allocation, therefore, the Article 8 assessments do not require a common set of objective metrics that can be compared across countries.
A more qualitative format that focuses on the specific strengths and weaknesses of each Member State, developed in a collaborative fashion, could be more appropriate.

Regulation 2022/2371 and the revised ECDC mandate address changes in the European health security regarding surveillance, data sharing, and epidemic intelligence at the Union level, and every Member State must have some level of competence in these areas, and at a minimum must have the capacity to interact with ECDC and other countries and international organizations.
The legislative changes also address coordination between public health and the healthcare delivery sector in the Member States.

Advances in qualitative assessment methodology

There have been several important advances in qualitative assessment methods in the last decade or two. This includes the development of the WHO Monitoring and Evaluation Framework (MEF), as well as guidance for conducting Simulation exercises and After-Action Reviews (AAR). The considerable experience with SimExs and AARs has been documented globally and in Europe. The COVID-19 pandemic accelerated this trend with the development of guidance for Intra-Action Reviews and the publication of the results.

Over the same period, there has also been considerable use of the WHO's Joint External Evaluation (JEE) process, and in 2022 the JEE tool was revised to reflect this experience as well as lessons learned during the COVID-19 pandemic.

Furthermore, in an analysis of 55 JEE assessments that were publicly available in March 2018, Gupta and colleagues found strong correlations between JEE performance and metrics of both health outcomes and health systems' performance, suggesting that the JEE is likely accurately measuring the strength of IHR-specific, public health capabilities.

In parallel with the development and use of these methods, public health researchers have developed a growing understanding of how to do rigorous qualitative assessments of public health emergency preparedness.

Experience with the JEE process, simulation exercises, and after- and intra-action reports over the last decade has proven the value of qualitative approaches to assessing PHEP. This experience also has shown that such qualitative approaches are most likely to result in meaningful learning if they:

1. employ a structured process;
2. are focused on specific incidents that are selected for their learning value;
3. are focused on pre-identified capacities and capabilities of interest at an appropriate level of generalization;
4. are conducted with appropriate time for reflection;
5. involve the full range of stakeholders involved in managing public health emergency;
6. involve external professional peers;
7. employ a no-fault systems framework, with full buy-in from leadership;
8. employ rigorous tools such as simulation exercises, facilitated lookbacks, and root cause analysis.

Criteria to improve the rigor and validity of qualitative assessments developed for AARs can also be usefully applied to other qualitative assessment methods.

Proposals for the development of preparedness assessment methods

Considering the requirements and expectations of Regulations 2022/2370 and 2022/2371, the following proposals in the development and preparedness assessment methods are suggested.

The first one, adopting the 7-1-7 approach for use in ECDC visits to Member States, relates primarily to the surveillance and epidemiologic intelligence focus of this analysis, but also addresses other public health emergency preparedness capacities and capabilities. The second one, developing stress test methods, starts from a methodology under development in the healthcare sector and broadens it to include coordination between public health and the healthcare delivery system. The third one, using a peer assessment process for the Article 8 assessments, builds on the advances in qualitative methods in recent years. While this process would address the full range of preparedness capacities and capabilities, its priority implementation should focus on surveillance and epidemic intelligence and on health sector coordination, the most critical areas addressed in the current analysis.

Adopt the 7-1-7 approach for use in visits to Member States

The 7-1-7 metric of the speed with which a system detects and responds effectively to threats is increasingly being used internationally as a means of assessing countries' ability to detect and respond effectively to an emerging public health threat.(84) Measuring a country's ability to respond requires review of how all elements of the global health security system work together to detect and respond to disease threats. This includes laboratories, surveillance and epidemic intelligence, but also health coverage and leadership. Therefore, continuously evaluating and improving timeliness can identify performance bottlenecks and help to accelerate progress, improving detection speed and response quality.(85) Establishing objectively verifiable benchmarks will give countries clear guidance, will give international institutions, other countries, and donors a clear pathway forward for measurement, accountability, and improvement.

For these reasons, a 7-1-7 analysis can provide useful information during the ECDC visits to Member States required under Article 8.

One of the primary strengths of timeliness metrics is that, unlike most capacity measures, they examine how public health systems perform in practice – in other words, they measure capabilities rather than capacities.

Performance in routine events may not indicate that a system is well prepared for more serious public health emergencies. Apparently, though, good performance during routine events is a necessary but not sufficient indicator that a system is prepared for more complex health emergencies.

The practice base on which systems are assessed using the 7-1-7 metric, however, ranges from routine infectious disease outbreaks caused by well-known pathogens to complex public health emergencies

such as Ebola in West Africa and COVID-19.(86) To improve comparability across countries, ECDC could specify in advance the set of outbreaks on which the metric would be calculated.

The SPAR tool already includes indicators relating to surveillance systems in general, and specifically regarding health care-associated infections (with a focus on antimicrobial resistance) and for zoonotic diseases (in relationship to the One Health approach). Developing specific approaches to operationalizing the 7-1-7 metric for these surveillance approaches, e.g. defining key terms, could provide a database of internationally comparable results and benchmarks. It would also generally fit into the increased emphasis on surveillance and epidemic intelligence in the new European health security framework.

Although they seem precise and objective, timeliness metrics depend on complex judgments about when milestones were achieved, so concerns about both reliability and validity are common. Incorporating 7-1-7 measures into ECDC's country visits would bring external observers into the process, and thus help to improve the objectivity of the metrics.

Develop stress test methods focusing on public health and healthcare services coordination

As previously mentioned, the revised ECDC mandate tasks the ECDC with developing "exercises, stress tests, in-action and after-action reviews, and support and complement Member States in those activities, and to organize additional actions to address gaps identified in preparedness capacity and capability." Regulation 2022/2371, on the other hand, calls for stress tests both in Article 5, which is about the Union-level prevention, preparedness, and response plan and in Article 7.

However, no clear definition of stress tests is provided, and in in this context the term should be referred to specific simulations designed to assess the response to a public health crisis as described below.

Many organizations use exercises in which they simulate their response to a hypothetical event to raise awareness, practice, or train. Similarly, exercises are also useful tools for assessing a system's ability to respond to emergencies and identifying weaknesses. The resulting information can then be used to strengthen preparedness capabilities. Such exercises may be used at each stage of emergency preparedness development to test the practicality, adequacy, sufficiency, and efficiency of proposed plans and procedures. For example, some researchers found that, although they need further evaluation and standardization, simulation exercises are an important tool for training and for improving disaster planning and response.(87)

Drills and exercises also can provide an important source of insight into how systems and capabilities might perform under realistic circumstances, and so how capacities might translate into operational capabilities. For example, the findings of a review of 17 simulation exercises (and 2 AARs) conducted in the EU between 2005 and 2018, showed as a result of these exercises, most of which were focused at the Union rather than Member State level, the need for changes in the EU regarding improved information exchange tools, clearer mandates for emergency coordination, procurement and stockpiling of medical countermeasures, and streamlined public communication. Indeed, eight out of the ten early lessons learnt during the COVID-19 pandemic had been raised earlier as recommendations in these exercises. The study found that simulation exercises are valuable instruments to assess the functionality of preparedness and response mechanisms, point out important gaps as well as to train and raise awareness on health emergencies.

More appropriate for quality improvement and resource allocation than accountability, these tools should be regarded as complementary to existing IHR monitoring tools at national level and possibly other monitoring tools at regional level in the EU.(88) Copper and colleagues found similar conclusion in their review of 117 SimExs and 63 AARs supported by the WHO from 2016 to 2019.(89)

Simulation exercises can also be useful in assessing system-level preparedness. With the goal of identifying gaps in public health preparedness at the local level in California, a team from the RAND Corporation developed the following approach. First, a team of researchers conducted a two-day site visit to nine counties. On the first day, the researchers interviewed key informants such as the public health director, the director of communicable disease control, a senior epidemiologist, a fiscal manager, a local political official, representatives of the medical community and emergency medical services departments.

These interviews provided information about how the public health system was organized and financed, as well as existing preparedness plans and challenges. On the second day, the team conducted a tabletop exercise simulating a smallpox outbreak or a diabetes crisis. In each jurisdiction, 15-18 participants similar to those who were interviewed, participated. Two facilitators followed a written discussion guide, tailoring the discussion to the group's response in each step of the exercise; a third individual took detailed notes on all aspects of the discussion. At the end of the exercise, the facilitators and participants compared the response to a list of public health emergency preparedness capabilities and identified critical gaps in that county.(90)

This was regarded as a simulation exercise, but might also considered a stress test, as discussed below.

Stress tests are simulations designed to replicate real-life events that can cause a crisis. The term is commonly used in the context of the financial sector, but it has several implications also for healthcare.(91)

For this reason, in the context of PHEP, stress tests are used to simulate emergencies such as pandemics, natural disasters, or bioterrorism attacks.(92) Their primary goal is to identify weaknesses and gaps in emergency response plans, communication channels, resource availability, and workforce capacity to improve the preparedness of the health system.

Stress tests can be conducted at different levels of the health system, from individual hospitals to entire health systems. The methodology and scope of stress tests vary depending on the goals and resources of the health system. For instance, a stress test could focus on evaluating the preparedness of hospitals in a region for an influenza pandemic or the preparedness of a health system to respond to a terrorist attack.(93)

Unlike areas such as banking or financial markets, in which stress tests rely on mathematical models to describe the response to the stressor, in public health, the response must specifically consider the thinking and actions of different stakeholders and sectors, which adds a significant level of complexity within health systems. The WHO recognizes the importance of stress tests in health systems. In its guidelines for health emergency and disaster risk management, the WHO recommends that health systems conduct regular stress tests to evaluate their preparedness and identify areas for improvement.(94)

The guidelines emphasize the importance of involving all stakeholders in stress tests, including healthcare providers, emergency responders, and public health officials, to ensure that all parties are familiar with each other's roles and responsibilities and that communication channels are established.

Looking back on the COVID-19 pandemic, some analysts have identified concerns with the resilience of national health systems and called for shared monitoring of these systems' preparedness.(95)

As countries seek to learn from the COVID-19 crisis and increase their resilience for the future, evaluations are important tools to understand what worked or not, why and for whom.(96)

The European Commission's Expert Panel on effective ways of investing in health recommended resilience testing of the health systems of European Union Member States.(97)

Borrowing on the financial system and other sectors experience, the OECD has called for the development of stress tests of national health systems.(76) The European Observatory on Health

Systems and Policies, in collaboration with OECD, is currently pilot testing one such approach.[11] The process begins with the development of a scenario that presents a shock to the health system. The shock could be a pandemic or similar public health emergency, a long-term crisis such as the emergence of anti-microbial resistance, or a major change in national healthcare legislation. A team of external observers then meets with national decisionmakers to discuss their likely response and the ability of existing systems to respond.

Unlike the stress tests used in the financial industry, which are based on economic models, health-sector tests would also factor in leaders' decision-making. The result is a report that identifies system gaps that should be addressed.

There are various types of simulation exercises and stress tests that can be used in PHEP. Some of the most common types include the following.

- Tabletop exercises: they are scenario-based simulations that involve key stakeholders in the health system to evaluate their response to a hypothetical crisis. The participants discuss a scenario and evaluate their roles and responsibilities, communication channels, and resource availability. Tabletop exercises are especially useful in evaluating the coordination and collaboration among stakeholders in the health system.
- Functional exercises: they involve simulated real-time responses to hypothetical crises. They are designed to test the operational capabilities of the health system in a controlled environment. Participants in functional exercises respond to the scenario as if it were happening in real-time and evaluate the effectiveness of their response. Functional exercises are useful in evaluating the capacity of the health system to respond to a crisis.
- Full-scale exercises: they involve real-time simulations of a crisis in a realistic environment. Participants respond to the scenario as if it were happening in real-time, and the exercise is designed to evaluate the capacity of the health system to respond to a crisis in a realistic environment. Full-scale exercises are useful in evaluating the effectiveness of the emergency response plan and identifying gaps in the health system's preparedness.
- Stress tests focus on hypothetical scenarios, during which it would be difficult for the health system to maintain its essential function of providing services to protect population health. The stress test explores approaches to effectively manage acute and chronic events (related to pandemic, climate, economic, systematic, or other) and conditions that could directly impact health systems with impact on health outcomes and/or health system functioning.(98)

[11] The EU4Health Programme is funding joint work between the OECD and the European Observatory on Health Systems and Policies to test resilience scenarios and produce a handbook.

While simulation exercises and stress tests are a valuable tool in PHEP, they do have limitations, the most important being that they are simulations and may not fully replicate the conditions of a real-life emergency. In a real-life emergency, there may be unexpected challenges and circumstances that were not accounted for in the stress test.

Regarding the methods mentioned above, the main limitations can be summarized as follows.

- Tabletop exercises are useful in evaluating the coordination and collaboration among stakeholders in the health system, but they may not accurately reflect the response in a real-life crisis. The hypothetical scenarios used in tabletop exercises may not fully encompass the complexities of an actual crisis, and participants may not respond in the same way. Additionally, tabletop exercises may not provide the same level of urgency and stress as a real-life crisis, which may impact participants' response.
- Functional exercises involve simulated real-time responses to hypothetical crises, but they may not capture the same level of stress and urgency as a real-life crisis. Moreover, functional exercises are resource-intensive and may be challenging to organize, which may limit their use.
- Full-scale exercises involve real-time simulations of a crisis in a realistic environment, so they may be challenging to organize and execute due to their resource-intensive nature.
- Designing hypothetical scenarios could compromise the scale and comprehensiveness of a real event. Moreover, the duration of a real event – such as COVID-19 pandemic can also be underestimated in the scenario assumptions.

Sometimes the term “shock tests” is used to describe a similar if not identical approach. However, while both types of tests identify weaknesses in the system and use similar tools, it is possible to differentiate them in their focus and purpose.
Stress tests evaluate the capacity of the system to cope with expected stressors, such as an increase in demand for healthcare services, a shortage of health personnel or a lack of critical equipment before they occur, allowing healthcare systems to take corrective actions; shock tests evaluate the system's ability to respond to unexpected events, such as pandemics, natural disasters, or other crises that can overwhelm healthcare resources and infrastructure.

Another difference is the level of resources required to conduct the tests. Stress tests are typically less resource-intensive than shock tests and can be conducted more frequently, while shock tests are more

resource-intensive than stress tests and may not be feasible for all healthcare systems. Both types of tests have strengths and limitations, and the choice of test will depend on the specific goals and circumstances of the healthcare system being evaluated.

Additionally, Regulation 2022/2371 not only lack a clear definition of stress test but is also somewhat ambiguous about the meaning of "health systems," referring in some paragraphs only to the healthcare delivery system (i.e. hospitals and other facilities, physicians and other professionals, etc. who provide healthcare to individuals), while elsewhere the larger health sector, which includes governmental public health agencies. Their interaction of the actors is, therefore, a critical point and ECDC should include stress tests focusing on their coordination as a key element in the assessment process.

On the basis of previous experience, the following methodology could be a preliminary model focusing on public health and the healthcare services coordination, to be further expanded.

1. An assessment team composed by qualified researchers, could conduct a site visit to the Member State in order to identify and interview key informants such as the public health directors, director of communicable disease control, senior epidemiologists, local political officials or representatives of the medical community and emergency medical services departments. Interviews should provide information about how the public health system is organized and financed, as well as existing preparedness plans and challenges.
2. The assessment team should then define the participants and proper tools, such as tabletop exercises, to simulate specific outbreaks or medical crisis.
3. Facilitators of the assessment team should follow the exercise with a written discussion guide, tailoring the discussion to the group's response in each step of the exercise while an external individual should take detailed notes on all aspects of the discussion.
4. At the end of the exercise, the facilitators and participants should compare the response to a list of public health emergency preparedness capabilities and identified critical gaps in that county.

The structure of stress tests and the assessment checklist to highlight specific capabilities gaps should be standardized within ECDC to have a common framework.

Use a peer assessment process for country assessments

The ECDC country visits to conduct Article 8 assessments required under Regulations 2022/2370 and 2022/2371 should take place every 3 years. Countries have nine months after the assessments to respond to the recommendations by preparing an action plan and implementing actions. These assessments are focused on quality improvement rather than accountability and consequently require a qualitative approach. In this sense, the Article 8 assessments can address issues not fully covered by the standardized Article 7 reports, such as changes in national preparedness plans that are required under Article 6.

In this context, a qualitative assessment process similar to the WHO's JEE was the starting point for developing this process. This process incorporates several practices from the qualitative research toolkit, including the use of external peer assessors, that are known to strengthen the validity and reliability of the results. The ECDC's process for assessing communicable disease control and prevention in EU enlargement countries and Assessment tool for joint One Health country visits in relation to antimicrobial resistance, as well as the WHO's Universal Health and Preparedness Review (UHPR) employ similar methods.

The JEE process begins with a self-evaluation completed by the country with multisectoral engagement. This can be very resource intensive. In the EU setting, the elements of the Article 8 assessments could be more closely related to the Article 7 metrics (which are intended to incorporate the SPAR metrics), leading to less duplication of effort. However, the EU legal framework requires a multisectoral approach in these assessments which obviously increases the complexity of the process.

Another way to reduce the burden of the self-study portion would be to limit the breadth of the topics covered. Under Article 8, the focus of ECDC country visits could be narrowed to specific areas of preparedness, as needed (but the same for all countries). For instance, the choice could be based, in collaboration with the Health Security Committee, on weaknesses identified in the Member State's Article 7 report. Alternatively, there could be a different substantive focus for all Member States in every three-year cycle. Given the attention to surveillance and epidemic intelligence in the revised European health security framework, this might be the first such topic. For similar reasons, future cycles might focus on health sector coordination and/or antimicrobial resistance.

The material to be reviewed for ECDC country visits would include the Article 7 reports. However, because the goal is improvement rather than accountability, the focus would be on improvements over time (or lack thereof) rather than comparisons across countries. Article 8 assessments could also address subnational capacities and capabilities, as well as coordination within and among countries, in a way not covered in the standardized Article 7 reports. In addition to Article 7 reports, the material to be reviewed could include findings from AARs as well as results of 7-1-7 analyses as already described. Reports from simulation exercises that have been completed, including stress tests should also be included.

One of the challenges of employing a JEE-type process is identifying qualified external peer observer, which can bring new perspectives to the analysis and improve their objectivity, also providing the opportunity to share learnings across countries. Peer assessors, however, must be carefully chosen to have the appropriate subject matter expertise and be trained in assessment methods. There can also be sensitivities in having individuals from other countries involved in the assessments. Consequently, the initial round of country visits might be staffed with ECDC assessors.

With time for identifying appropriate individuals, subsequent rounds could involve assessors from other EU Member States. In this regard, the development of the EU Health Task Force presents an opportunity. Employing experts operating under the Task Force would be an opportunity to train and socialize the health professionals involved, share learnings across countries, and build a strong European network of PHEP experts.

DISCUSSION AND LESSONS LEARNED: THE EXPERIENCE OF EMILIA-ROMAGNA

The COVID-19 pandemic has spread profoundly across global health systems, but regions like Emilia-Romagna in Italy, especially its capital Bologna, experienced pronounced impacts.

With Italy being the first Western country severely affected by the virus, Emilia-Romagna witnessed significant strain on its healthcare infrastructure. Despite not being the primary epicentre, the region had one of the highest numbers of cases in Italy during the early stages of the pandemic.(99)

The health infrastructure of Emilia-Romagna, traditionally lauded for its efficiency and quality, found itself grappling with an unprecedented surge in patient numbers. Hospitals, particularly in Bologna, faced bed shortages, especially in Intensive Care Units (ICUs), necessitating the rapid conversion of general wards into COVID-19 units.(41)
This adaptation, though commendable, came with challenges because readjustments led to resource constraints, from essential medical equipment to trained personnel, potentially compromising care quality in certain instances.(63)
Another tangible consequence in the healthcare sector was the displacement of attention from non-COVID-19 patients: with resources being redirected to combat the pandemic, there was a noted decline in routine medical activities. One of the most notable impacts was the postponement or outright cancellation of elective surgeries. As it happened on other countries, hospitals of Bologna faced a sharp decrease in surgical procedures by up to 75%, especially those deemed non-urgent.(100) Furthermore, outpatient visits, vital for disease monitoring and management, saw a dramatic decline, raising concerns about potential health complications down the line.(101)

Emilia-Romagna's robust cancer care framework, for instance, witnessed disruptions, with oncology departments recording decreased diagnostic procedures and deferred treatments.(102)
Similarly, as it happened in other regions, there was a significant decline in non-COVID-19 emergency department visits, indicating potential underdiagnosis or untreated emergent non-COVID conditions.(103) While the global reallocation of resources was necessary given the pressing demands of the pandemic, the long-term consequences on patient health, especially those requiring timely interventions, cannot be overlooked and will require great attention in the upcoming future.

Another area of concern was the potential increase in nosocomial infections and the high transmissibility of the SARS-CoV-2 necessitated rigorous infection control measures.(104) The hospital network of Bologna had thus to swiftly implement stringent sanitation protocols and restrict visitor access, strongly changing the patient-care system.

The pandemic's impact was not limited to clinical services alone; research activities, particularly clinical trials, were disrupted. Hospitals in Bologna that were actively involved in clinical research faced challenges ranging from recruitment halts to compromised data integrity due to missed follow-ups.
Furthermore, the human aspect of healthcare, often understated, was profoundly affected. Medical professionals in Bologna faced burnout, psychological distress, and moral injury, especially when confronted with overwhelming patient loads and challenging triage decisions.(105)
The emotional toll of witnessing heightened mortality, often without the solace of familial presence, left indelible scars on the city's healthcare fraternity.
Financially, the healthcare sector in Emilia-Romagna grappled with the dual challenges of escalating costs associated with pandemic management and reduced revenues from the suspension of elective procedures and outpatient visits. Despite the Italian government's allocation of emergency funds, the economic sustainability of some healthcare institutions in the region became a matter of concern.

However, it is essential to recognize the adaptability and resilience displayed by the healthcare system of Emilia-Romagna and Bologna. Initiatives like the bolstering of telemedicine platforms and the establishment of temporary field hospitals underscored an agile response to an evolving crisis.(106)
Additionally, collaborative research efforts within the region played a pivotal role in contributing to the global understanding of the virus's pathology, transmission, and potential treatment strategies.
In particular, the experience of the Local Health Authority of Bologna highlighted the pivotal role of the city in the regional response to the pandemic.
The Maggiore Hospital, the largest of the local network, was on the first hub for COVID ICUs and was quickly able to provide a support for other regional hospitals. (107)
Operating rooms and endoscopy units promptly defined specific pathway for COVID patients, minimizing the risk of viral transmission. (108) (109)

Overall, while the COVID-19 pandemic undeniably strained the healthcare sector in Emilia-Romagna, and specifically in Bologna, it also showcased the region's ability to innovate under

pressure, collaborate on an unparalleled scale, and maintain its commitment to patient care amidst adversity.(67)

On the basis of these local experiences, the importance and complexity of subnational structures for surveillance and epidemiologic investigation, and the challenges of adapting existing and developing new surveillance and response systems emerged as topical issues during the pandemic.
To address concerns identified in the early phase of the pandemic, the Italian plan for the prevention and response to COVID-19 in the autumn-winter season published in October 2020 described an integrated surveillance system combining epidemiological data, case based and aggregated data, and microbiological data, with the integration of data in the National Epidemic Intelligence Network.(58)
In June 2021, the Epidemic Intelligence Network received legal endorsement as an event-based surveillance system to coordinate all activities aimed at the early identification of risks in public health, their validation, evaluation, and investigation that 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.

Additionally, as a summary of the lessons learned for the development of the Italian PHEP strategy, the national plan for preparing and responding to an influenza pandemic (Piano strategico–operativo nazionale di preparazione e risposta a una pandemia influenzale - PanFlu 2021 – 2023) was issued at the beginning of 2021, emphasising the relevance of sharing data and implementing operational protocols/tools in the inter-pandemic phase.(110)
This plan was adopted by the Emilia Romagna region and implemented in 2022, incorporating both local and international recommendations, mainly from ECDC and WHO. In particular, the plan underlies the role of stress tests and simulations in order to properly assess and evaluate the actual PHEP of the system, and the first regional exercises are planned by the end of 2023.

In conclusion, the COVID-19 pandemic highlighted the need for holistic, forward-looking strategies to fortify the healthcare system against future challenges. PHEP systems need updated logic frameworks able to encompass all their key areas and robust methodological tools to continuously test them.
The findings and the proposals reported in this thesis may represent an initial contribution towards that direction.

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