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Time to reconceptualise health systems

The COVID-19 pandemic continues to expose tremendous vulnerabilities in every country’s health system. It also highlights deficiencies in existing conceptualisations of health systems that overlook health security and health promotion. The global spread of COVID-19 has focused attention on roles of health systems in managing health emergencies. At the same time, more than 70% of deaths are now caused by non-communicable diseases. Investing in both health security and health promotion is acute and urgent. Considering the goals of health security and health promotion separately, however, frames policy decisions as making investments in one or the other, which is a false dichotomy obscuring the interconnected and central role of health systems in addressing both goals and achieving universal health coverage.1,2

When health systems contribute to managing epidemics, they create healthy populations, which in turn are better able to mitigate continuing and future epidemics. For example, communities with high burdens of obesity and chronic diseases have greater COVID-19 risks, whereas healthier populations are less susceptible to COVID-19. But a singular focus on managing health emergencies can also limit efforts to create healthy populations. COVID-19 control measures can reduce physical activity, create social isolation, and cause economic hardship among other implications.

COVID-19 will not be the last pandemic. Health systems need to prepare for new and evolving crises. Policy makers also need to be empowered to address health risks beyond the health sector. Yet a predominant focus on individual health care within existing health systems frameworks has neglected community engagement and ignored how policies, programmes, and systems could be designed to address health emergencies and create healthier populations.

Health systems frameworks are contested products of their time.3 Existing frameworks predate the Sustainable Development Goals and COVID-19 eras, and largely focus on delivering clinical services responding to people’s rightful demand for care. However, health systems should be reimaged in light of the pandemic to go beyond this, and better serve the purpose of preparing and responding to anticipated (and unanticipated) future hazards and risks, and to produce healthier and more resilient societies. This reconceptualisation matters because frameworks shape policy and investments. Reconceptualising health systems means shifting future investments into these functions to strengthen health systems and prevent further fragmentation of competing parallel investments in health security and health promotion.

The Alliance for Health Policy and Systems Research is seeking to reimagine health systems frameworks to better address these goals in an integrated way. Building on ongoing efforts to overcome fragmented health systems,4 the Alliance’s 2022 flagship report will reassess existing frameworks, develop an integrated framework, and provide approaches for action. We hope to move beyond the false dichotomy of investing in health security or health promotion and instead focus on how strategic investments reinforce each other to strengthen health systems that move towards universal health coverage and achieve Sustainable Development Goal 3 to ensure health and wellbeing.

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HERA: a new era for health emergency preparedness in Europe?

After the first wave of COVID-19 in Europe, the European Commission (EC) committed to take bold actions in preventing and managing similar threats in the future.5 The EC recognised that there was a lack of capability in the EU regarding the demand-to-supply dimension of devices, commodities, and products essential for preparedness and response. Consequently, the EC proposed to create a new agency devoted to well organised stockpiling of preparedness and response tools as countermeasures: the European Health Emergency Preparedness and Response Authority (HERA). Public consultation was open until May 12, 2021, and the exact remit of HERA will be set out in a legislative proposal later in 2021. We believe HERA should embrace the global dimension of health threats and the three main components of preparedness (ie, risk assessment, risk management, and risk communication), in close collaboration with other existing initiatives.

Published Online
May 24, 2021
https://doi.org/10.1016/S0140-6736(21)01019-9
For non-communicable diseases data see https://www.who.int/data/gho/data/themes/topics/indicator-groups(indicator-group-details/GHD/total-ncd-mortality

Published Online
May 17, 2021
https://doi.org/10.1016/S0140-6736(21)01107-7

For more on HERA see https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12370-European-Health-Emergency-Preparedness-and-Response-Authority-HERA_en

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Panel: A five-prong bundled model for health emergency preparedness

• Technological innovation and rapid response to market and regulatory challenges
• Harmonisation of policy development and adaptable policy implementation at national and sub-national levels
• Monitoring, preparedness and response mechanisms
• Horizon scanning to adequately detect cross-border threats and hazards in Europe or elsewhere and to monitor and evaluate new countermeasure products, devices, and technologies
• Education and training with the contribution of academic and public health institutions offering cross-disciplinary didactic plans

EU agencies (eg, the European Centre for Disease Prevention and Control [ECDC] and the European Medicines Agency [EMA]) and relevant non-EU agencies (eg, WHO), in a five-prong bundled model (panel). HERA, through effective stockpiling, could incentivise a more coherent response to emergencies and simultaneously strengthen all key elements of a comprehensive and timely response to health emergencies in the EU and elsewhere.

First, HERA must support technological innovations and rapid response to market and regulatory challenges, starting with stockpiling and distribution mechanisms of key response countermeasures (eg, protective equipment, medical devices, reagents, medicines, vaccines) and protocols. This response will require a stimulation of technologies and identification of solutions to overcome market and regulatory challenges for existing or new products. Essential to this response is facilitating equitable global access by removing or addressing existing barriers and promoting transparency in the procurement and costs of these products. A strong market intelligence focus is needed to monitor available stocks of countermeasures and to ensure that market blockages for needed supplies are detected and addressed where necessary. As stockpiling and emergency preparedness data are sensitive, interlinkages with civil defence bodies will be necessary.

Second, HERA could bring member states together to pursue common and homogeneous ways for flexible policy formulation and adaptable implementation at national and sub-national level in close collaboration with other EU (eg, ECDC and EMA) and non-EU entities (WHO, Africa Centres for Disease Control and Prevention [CDC] and US CDC) that are crucial in the international pandemic response. This harmonisation of policy development should include coordinated stockpiling rules, development of joint operational procedures, and essential item lists for an effective EU and global response. Harmonisation of policies across decentralised or federal systems where difficulties exist in ensuring a coherent response can thus be addressed. Emphasis is also needed in developing and implementing consistent tools for timely adaptive risk communication to the general public on risks and mitigation strategies to prevent undermining of shared policy frameworks. Establishing an accountability framework with a clear description of responsibilities will help identify focal points—eg, for distributions of commodities and furthering targeted education and training of personnel.

Third, monitoring, preparedness, and response mechanisms should be regularly tested to allow an early and bold response. Weaknesses should be identified with preparedness assessment tools. Adherence to established WHO recommendations for 2005 International Health Regulations self-assessment and regular external evaluation and the United Nations Office for Disaster Risk Reduction’s Sendai Framework for Disaster Risk Reduction 2015–2030, coordinated jointly by agencies such as HERA and ECDC, should become a condition to benefit from stockpiling.

Fourth, horizon scanning activities will require strengthening and establishment of a robust and accessible joint EU and WHO surveillance system, managed by ECDC, with the capacity to identify cross-border threats early, and a monitoring framework in collaboration with EMA to gain knowledge and assess countermeasure products, devices, and technologies under development worldwide in a timely fashion. Both surveillance and monitoring require backing by strong political commitment and engagement with other EU agencies like ECDC and EMA, as well as global initiatives for pandemic preparedness and WHO. Use of data science and digital technology (eg, artificial intelligence) is important to predict future scenarios for risk mitigation. Technologically advanced horizon scanning tools would promote a more precise global health response.4

Fifth, building fresh and specific competence for health and non-health personnel across the EU through education and training is fundamental. Training activities should focus on augmented surveillance and preparedness monitoring, pursuing cost-effective policies, improving bio-pharmaceutical development and production, developing and using advanced tools for horizon scanning, and studying emerging health threats. Through the Erasmus+ programme, for example, knowledge, skills, and experiences can be exchanged, thereby harmonising and enriching the way preparedness strategies are developed and applied. European universities and research institutions have much to offer through programmes of strategically important research, platforms for specialised technical knowledge, and additional know-how on risk and mitigation strategies, as well as education and training opportunities for future experts (eg, in biomanufacturing capacities). Multidisciplinarity, interdisciplinarity, and transdisciplinarity will be vital to solve complex public health emergencies of the future.

Finally, the bundled approach cannot be accomplished without two additional cross-cutting elements: promoting research and innovation for a preparedness agenda; and fostering...
international partnerships with non-EU countries, including low-income and middle-income countries, and stakeholders who are critical for timely communication and containment of global threats. These partnerships require a new vision for a well-structured bilateral and multilateral cooperation with all regions worldwide, starting with a closer engagement with WHO as a global supranational moderator. This approach will be equally attractive to partners outside the EU, as health threats might originate inside the EU and spread beyond its borders.

By bundling together these five components and the two cross-cutting elements, HERA can become a lighthouse in the EU and worldwide, equipping each member state for timely and effective response to emerging threats. This goal, however, cannot be achieved without a modern and sustainable global health approach that promotes a more just and equitable preparedness system. If, through HERA, the EU successfully implements an exemplary preparedness framework, the global community would enjoy efficient tools and a balanced architecture to boldly respond to future pandemics and emergencies.

The authors received no specific funding for this Correspondence. Rvl is a member of the Biotech companies in Europe combating AntiMicrobial Resistance Alliance. TB reports grants from Horizon 2020, EIT Health, German Research Foundation, US National Institutes of Health, German Ministry of Education and Research, Alexander von Humboldt Foundation, Else-Kröner-Fresenius Foundation, Wellcome Trust, Bill & Melinda Gates Foundation, KfW, UNAIDS, and WHO. All other authors declare no competing interests. FC, AP, and MR contributed equally.

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**Patient involvement in regulation: an unvalued imperative**

There is now an imperative for medical regulators to involve patients and the public across the range of their work, in the same way as it has become accepted practice to involve patients in decisions about their medical care, as part of mainstream existentialist philosophy. However, patient involvement remains largely unvalued for its influence on decision making about approval of medicines and medical devices, or their withdrawal from use because of safety signals. Regulatory agencies worldwide are grappling with the range and complexity of ways in which patients and the public might be involved in regulation, but they also need to evaluate the outcomes of their efforts.

In the UK, a government-level report about the health-care system’s response to safety concerns emphasised the need to engage with patients throughout the regulatory lifecycle of medicinal products. In the USA, the Food and Drugs Administration has made patient engagement a priority. Such engagement includes patient input to guide clinical trial design during product development, decisions about market approval, provision of information about the effects of products (especially adverse events), and decisions about whether safety signals justify restrictive action.

Engagement of patients can be in advisory or decision making groups, which enables them both to relate their experiences and to proffer their opinions. The COVID-19 pandemic has transformed the ways committee meetings, focus groups, and other discussion forums typically take place: video links make it much easier for people to become involved. Training and support remain essential to help lay people join groups of professionals in discussion on an equal footing.

In a wider context, patients’ experiences can contribute to regulation through their reporting of adverse events and especially through patient reported outcomes. Rapid advances in mobile technologies are facilitating this reporting to an extent that could not have been imagined a few years ago.

It could be argued that involving patients and the public in regulatory decision making is a valid endpoint or outcome in itself, and that, without further examination, it is a good and proper thing to do. However, such involvement will be influential in deciding which health-care interventions society receives, so it ought to