

Assessment of the Implementation of the International Health Regulations during the COVID-19 Pandemic: Portugal as a Case Study

Avaliação da Implementação do Regulamento Sanitário Internacional durante a Pandemia de COVID-19: O Caso Português

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ABSTRACT

Introduction: The International Health Regulations (IHR) were developed to prepare countries to deal with public health emergencies. The spread of SARS-CoV-2 underlined the need for international coordination, although few attempts were made to evaluate the integrated implementation of the IHR's core capacities in response to the COVID-19 pandemic. The aim of this study was to evaluate whether IHR shortcomings stem from non-compliance or regulatory issues, using Portugal as a European case study due to its size, organization, and previous discrepancies between self-reporting and peer assessment of the IHR's core capacities.

Methods: Fifteen public health medical residents involved in contact tracing in mainland Portugal interpreted the effectiveness of the IHR's core capabilities by reviewing the publicly available evidence and reflecting on their own field experience, then grading each core capability according to the IHR Monitoring Framework. The assessment of IHR enforcement considered efforts made before and after the onset of the pandemic, covering the period up to July 2021.

Results: Four out of nine core IHR capacities (surveillance; response; risk communication; and human resource capacity) were classified as level 1, the lowest. Only two were graded level 3 (preparedness; and laboratory), the highest. The remaining three (national legislation, policy & financing; coordination and national focal point communication; and points of entry) were classified as level 2.

Conclusion: Portugal exemplifies the extent to which implementation of the IHR was not fully achieved, which has resulted in the underperformance of several core capacities. There is a need to improve preparedness and international cooperation in order to harmonize and strengthen the global response to public health emergencies, with better political, institutional, and financial support.

Keywords: COVID-19; Decision Making; Health Policy; International Health Regulations; Pandemics; Preparedness

RESUMO

Introdução: O Regulamento Sanitário Internacional (RSI) foi redigido de forma a preparar os países para lidar com emergências de saúde pública. Apesar de a propagação do SARS-CoV-2 ter sublinhado a necessidade de uma coordenação internacional, houve poucas tentativas de avaliar a implementação integrada das capacidades essenciais do RSI em resposta à pandemia de COVID-19. Neste estudo, tivemos como objetivo avaliar se as insuficiências na resposta à pandemia decorreram de lacunas na implementação do RSI ou do regulamento em si, utilizando Portugal como um estudo de caso europeu devido à sua dimensão, organização e histórico de implementação do RSI.

Métodos: Quinze médicos internos de Saúde Pública envolvidos no rastreio de contactos em Portugal continental interpretaram a efetividade de cada capacidade essencial do RSI, analisando documentos públicos e refletindo sobre a sua própria experiência no terreno, classificando cada uma de acordo com o Quadro de Monitorização do RSI. A avaliação da implementação do RSI considerou os esforços realizados antes e depois do início da pandemia, abrangendo o período até julho de 2021.

Resultados: Quatro das nove capacidades essenciais do RSI (vigilância; resposta; comunicação de riscos; e capacidade de recursos humanos) foram classificadas no nível 1, o mais baixo. Apenas duas foram classificadas no nível 3 (preparação; e laboratório), o mais elevado. As três restantes (legislação nacional, políticas e financiamento; coordenação e comunicação do ponto focal nacional; e pontos de entrada) foram classificadas como nível 2.

Conclusão: Portugal é um exemplo de como a implementação do RSI não foi totalmente alcançada, resultando num desempenho insuficiente de várias

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capacidades essenciais. É necessário melhorar a preparação e a cooperação internacional, a fim de harmonizar e reforçar a resposta global às emergências de saúde pública, com um melhor apoio político, institucional e financeiro.

Palavras-chave: COVID-19; Pandemias; Política de Saúde; Regulamento Sanitário Internacional; Tomada de Decisão

INTRODUCTION

Previous public health emergencies of international concern (PHEIC) have stressed the need for international coordination and the importance of the International Health Regulations (IHR). COVID-19, however, has proved to be a unique challenge to this legal instrument, especially in high-income countries, where infectious disease outbreaks are now rare.¹ This has highlighted the need for new perspectives and possible revisions of the IHR.

A country-level evaluation of IHR implementation during the COVID-19 pandemic may prove to be an important tool to assess whether the IHR are suited to deal with PHEIC, to clarify its strengths and weaknesses, and to determine whether any possible shortcomings were due to non-compliance with the IHR or if the issue lay in the regulations themselves.

The IHR were first adopted by the World Health Assembly in 1969 and later revised in 2005, after the SARS-CoV-1 outbreak in 2003.² As a legally binding instrument of international law, the IHR establish practices and procedures intended to prepare a country for public health emergencies and are currently enforced by a total of 196 states. Although the implementation of the IHR's core capacities was roughly estimated to be 75% in 2019, it is widely known that national-level discrepancies – including in high-income countries – limit the comprehensive understanding of the factual effectiveness of IHR to achieve its aims.³

In previous public health emergencies, such as the 2013 – 2016 West Africa Ebola virus⁴ and the 2009 H1N1 influenza virus,⁵ many comments were made about the implementation of the IHR. These regulations are supposed to facilitate global communication and cooperation, but they failed to properly assess the seriousness of these public health threats and their evolution over time, thereby delaying the necessary response. In order to reduce response time and for them to work as a global detection system, there is a need for all countries to comply with similar procedures and to provide more quality information to their national counterparts and international institutions.⁶

Due to its novel nature and the fact that it was the largest PHEIC since the inception of the IHR, COVID-19 posed significant challenges when it came to implementing them. Even though the IHR score – the State Party Self-Assessment Reporting Tool on the compliance with the IHR – was significantly associated with a reduction in the rates of COVID-19 incidence and mortality,⁷ some authors have pointed out failures and revision proposals, focusing on enhanced surveillance and mandatory reporting, transpar-

ency in PHEIC decisions, rapid public monitoring of state measures, and an increase in public health systems⁸ and in global funding mechanisms.⁹ Previous country-level testimonies also highlighted the need for multisectoral response and community-oriented approaches.^{10,11} An independent panel set up by the World Health Organization (WHO) to review this international health response considered the IHR a “conservative instrument that constrains rather than facilitates rapid action”.¹² The panel concluded that the IHR were not deficient, but that their implementation by member states and the WHO was inadequate.¹³

In this study, we aimed to show how the implementation of the IHR in Portugal can contribute to this debate and to the prospects of the international response to PHEIC. The State Party Self-Assessment Annual Report (SPAR) of IHR reported a compliance of 82% in terms of core capacities and of 100% regarding the Points of Entry [(PoE): ports, airports and ground crossings].³

However, a 2018 evaluation carried out in Portugal PoE showed that they met around 71% of the IHR capacities for PoE, highlighting a gap between the self-report and the peer assessment. This assessment detected training flaws in the working teams and an inability to detect unexpected Public Health problems, which might be due to a lack of continuous training and situation-specific contingency plans.¹⁴

In Portugal, the first COVID-19 case was detected on March 2, 2020. The Directorate-General of Health (DGS) led the country's response from the beginning, in close articulation with the government and social partners. While in the first wave, the indicators seemed to demonstrate a good country-level performance compared to Spain or Italy, in January 2021 Portugal ended up recording the highest number of daily confirmed deaths per million people in the world. By joining Public Health professionals directly involved in the local response to the pandemic, but not in its national management, we wanted to come up with an independent and critical view to underline whether shortcomings in the implementation of the IHR could be attributed to non-compliance with the IHR or whether the issue could be associated with the regulations.

METHODS

Portuguese public health medical residents played an important role throughout the COVID-19 pandemic, leading fieldwork and applying IHR and national guidelines locally. To evaluate IHR enforcement during the COVID-19 pandemic in Portugal, 15 public health medical residents

working in all regions of mainland Portugal thoroughly evaluated the IHR, taking into account publicly available evidence and their work experience during the pandemic.

The enforcement of International Health Regulations was assessed using the IHR Core capacity Monitoring Framework, which is the recommended checklist for monitoring the progress of IHR core capacity development.¹⁵ The tool was used to evaluate implementation in the eight core capacities and PoE. Potential hazards (zoonotic events, food safety, chemical events, and radiation emergencies) were not assessed in this study.

Public health medical residents were assigned to three groups. Individually, each group screened for available evidence on the eight core capacities and PoE component level requirements. Data sources included, but were not limited to, legislation, standard operating procedures, guidelines, regulations, other binding policies, and media news. The complete list of collected data sources is available in the Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/19887/15240>).

The three groups undertook a capability level analysis by following the framework's proposed methodology for scoring indicators and, subsequently, for assessing core capacity capability levels. Scoring results were level < 1 (foundational), level 1 (inputs and processes), level 2 (outputs and outcomes), and level 3 (additional achievements). The analysis of the attributed score to an indicator was not performed since the goal of this study was to assess the capability level achieved in the particular context of the COVID-19 pandemic and not to measure the country's progress towards the attainment of an individual core capacity.

Afterwards, two representatives from each group convened to discuss the results. After a new focused assessment of the evidence, the representatives agreed on a single final table as presented in the supplementary material.

Only measures already in place before the pandemic and those adopted from its onset until July 3, 2021 were considered in this analysis.

No ethics approval was necessary to undertake this study as it relies on publicly available secondary data.

RESULTS

The detailed checklist is available in the Appendix 1 (Appendix 1: <https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/19887/15240>).

Core capacity 1 – National legislation, policy & financing: Level 2

Every WHO member is legally bound to the IHR by international law. Portugal's legal structure possesses a series of mechanisms that regulate actions in this area, such as the Portuguese Constitution, the Social Security and Basic

Health Law, the Public Health Surveillance System, and the Public Health Emergency Center. Exceptional measures were also added to the regulatory framework in the form of two declarations of a national state of emergency. Level 3 was not granted as the country still falls short when it comes to regulatory and administrative enforcement of specific measures, such as yearly updates of IHR implementation status. Additionally, no global evaluations or audits were made of official proceedings or tools needed to implement the IHR.

Public health funding was allocated in the annual state budget, while further funding was distributed through the National Plan for the Expansion of SARS-CoV-2 Laboratory Diagnosis Capacity. These were complemented by the European Union Solidarity Fund and exceptional authorization for spending. Even though there was a strong financial response from the Portuguese government, no resources were clearly allocated to specific IHR activities.

Core capacity 2 – Coordination and national focal point (NFP) communication: Level 2

The Directorate-General of Health worked as the NFP, and it articulated with the Ministry of Health in a predefined structural organization. Technical standards were set out by the DGS, which designed a framework of cooperation with institutions from different sectors – including kindergartens, nursing homes, ports, and public transportation companies.

In addition, some information systems were optimized, and new ones were created, but there was no IHR-related awareness-raising for public health professionals. Annual updates of the IHR's implementation status do not exist or were not made public. There was no active IHR website and no IHR NFP functions were evaluated for effectiveness.

Core capacity 3 – Surveillance: Level 1

Although there is a list of mandatory, notifiable diseases, COVID-19 surveillance data were analyzed daily at the national and regional levels. There was also a 'red line monitoring report' which was published weekly by the DGS indicating potential measures to be taken. However, the 80% threshold for timely notification reports was not met in several periods after June 2020. Moreover, there was no information in the public domain that pointed to risk assessment notifications from the NFP to the WHO.

Event-based surveillance was not publicly reported in Portugal and was therefore hard to quantify. The country's surveillance system mainly relied on indicator-based surveillance, through the National Epidemiological Surveillance System (SINAVE), whose sources were notifications from physicians and labs.

Core capacity 4 – Response: Level 1

Although rapid response teams (RRT) were set up, they were severely lacking in human resources and basic equipment, not to mention regular, systematic simulation training. A national contingency plan (NCP) for the COVID-19 response was drafted and covered operational procedures and communication flows. However, there were gaps in leadership communication. The response was considered reactive rather than proactive.

Standard operating procedures (SOP) in COVID-19 case management were issued and updated as needed. COVID-only areas were set up at community and hospital levels and reference hospitals were identified. Case management training was offered to healthcare professionals, but its implementation and monitoring were not properly standardized. Twenty-four-hour telephone lines were set up for advice to the public and healthcare professionals.

The country's Program for Infection Prevention and Control (PPCIRA) has been considered a priority program since 2013. Several SOP on infection prevention and control for SARS-CoV-2 were issued for different contexts, including high-risk environments and population groups. Intensive care units were reorganized, and referral flows were created. Nevertheless, no systematic assessment of the effectiveness of the measures was conducted. Although the country had no formal healthcare professional safety program, some guidance was issued on the matter. An example of this was priority COVID-19 vaccinations for healthcare professionals.

COVID-19 disinfection and decontamination guidelines were drafted for healthcare services and other types of facilities.

Core capacity 5 – Preparedness: Level 3

The establishment of the National Public Health Council and COVID-19 response and vaccination task forces made expertise available. A national novel coronavirus preparedness and response plan was drawn up in March 2020 but was never updated. Mobilization of material and human health sector resources and exceptional recruitment of retired healthcare professionals were authorized at that time. Preparedness plans were drafted for the autumn and winter of 2020/2021 in anticipation of a larger-than-normal flow of patients. Service members and professionals from other sectors were put to work in contact tracing and case management. Medicines, medical devices and personal protective equipment (PPE) stocks were increased by 20%.

Portugal's cooperation with other Portuguese-speaking countries continued and an extraordinary aid deal was made with Cape Verde for the distribution of PPE. Financial contributions were made to Global Alliance for Vaccines and Immunization (GAVI) and COVID-19 Vaccines Global

Access (COVAX).

The Portuguese NFP participated in the ECDC Early Warning and Response System (EWRS), sharing information and expertise on COVID-19 surveillance and the IHR.

Core capacity 6 – Risk communication: Level 1

A COVID-19 risk communication plan was implemented during the pandemic and responsibility for the coordination of communication processes was assigned. There was an accessible source of information. Nevertheless, it is not clear if and how risk communication was assessed. This plan was never updated either.

Core capacity 7 – Human resource capacity: Level 1

Training needs were not assessed, and public health human resource planning did not meet the ratio of healthcare professionals per capita required by law.

In November 2020, the government decided to reinforce the early detection capacity of authorities and public health services and increase the number of vacancies in the public health medical residency program for 2021. However, the training program was neither monitored nor assessed.

The DGS offers one placement every year in the European Programme for Intervention Epidemiology Training (EPIET).

Core capacity 8 – Laboratory: Level 3

The country's reference laboratory for the diagnosis of SARS-CoV-2 was the National Health Institute Dr. Ricardo Jorge (INSA), which has an established laboratory diagnosis network as well as European and international accreditation. Minimal requirements for laboratories and standards for PPE and medical devices were available, but no public assessment of their enforcement seems to have been made.

There is the Portuguese Network of Laboratories for Influenza Diagnosis, and INSA is the national reference laboratory for all respiratory viruses. It is associated with the European Influenza Surveillance Network.

A number of guidelines on biosafety have been published since March 2020. The Portuguese Quality Institute (IPQ) and the Portuguese Accreditation Institute (IPAC) set the criteria for identifying laboratories qualified to assess the conformity of Portuguese-made PPE, medical devices, and masks. The INSA Emergency and Biopreparation Response Unit (UREB) was responsible for coordinating lab responses to public health risks. INSA has also coordinated the National Level 3 Biosafety Laboratory Network since 2010 and provides training to professionals in this area.

COVID-19 cases were recorded in SINAVE clinical and/or laboratory databases within 24 hours of a positive result.

INSA published reports on the evolution of cases in the

epidemic curve and transmissibility parameters $[R(t)]$. Since June 2020, it has also analyzed SARS-CoV-2 genetic diversity.

SINAVE is part of the European Surveillance System (TESSy) and Portugal participates in Nextstrain, an open-source global project that gathers and continuously analyses pathogen genome data.

Points of entry: Level 2

The DGS issued guidelines on procedures and surveillance at airports and seaports early in the pandemic response. Previous procedures and surveillance at PoE were well-established, with contingency plans in accordance with the IHR.

The COVID-19 response NCP determined the minimum requirements for the structure of national borders and trained staff. Specific guidelines and communication flows were developed, including direct communication between the international health authority for airports and seaports and the NFP.

Measures were increased at airports and seaports as needed. A list of high-risk countries was published and updated regularly in accordance with ECDC criteria. Authorized waypoints at land borders were determined and specific procedure guidelines were issued.

Routine surveillance procedures were implemented at PoE and management procedures for suspected and confirmed cases were determined. A COVID-19 aviation health safety protocol set out operational guidelines for the management of air passengers and aviation personnel.

PoE also included maritime circulation, and sea crew and passenger disembarking restrictions in Portuguese ports in March 2020. Portugal enforced air traffic restrictions and limitations on the free circulation of people in the EU, in accordance with decisions of the European Commission and European Parliament and Council. A passenger locator card was introduced in June 2020. The EU COVID-19 Digital Certificate was introduced in July 2021.

DISCUSSION

The main purpose of the IHR is to “prevent, protect against, control and respond to the international spread of disease” while “(...) avoiding unnecessary interference with international traffic and trade”. The interpretation of the different core capacities set in place in Portugal shows the extent to which the COVID-19 pandemic posed some major challenges to the implementation of the IHR. Level 1 was attributed to Surveillance (Core capacity 3), Response (Core capacity 4), Risk Communication (Core capacity 6) and Human Resource Capacity (Core capacity 7), as some outputs and outcomes designated for those areas were nonexistent. One clear example was the development of

an event-based surveillance system optimized for the early detection and monitoring of potential health threats (Core capacity 3); another was the need for overall optimization of human resources (Core capacity 7), by increasing the number of dedicated professionals, while simultaneously investing in a strong training component. Regular simulations are essential to develop people skills and to analyze, monitor and optimize the response.

Level 2 was attributed to national legislation, policy and financing (Core capacity 1), coordination and national focal point (NFP) communication (Core capacity 2) and Points of Entry. The findings on PoE were in line with those previously described by Sá Machado *et al.*¹⁴ The country could have promoted cooperative efforts between different authorities, while also allocating additional funds to IHR activities, including improved border control. Moreover, investment in improving the knowledge of Public Health professionals and the usage of effective communication platforms would have greatly improved the Portuguese response to COVID-19.

These findings are aligned with the conclusions from the WHO Review Committee on the Functioning of the IHR (2005) during the COVID-19 Response. The report outlined a common failure in most countries in three main areas: compliance and empowerment; early alert, notification, and response; and financial and political commitment.

In their review, the Committee stated that to improve compliance, IHR implementation needed to become a government priority, requiring sustainable financing nationally and internationally, along with a robust accountability mechanism.

This commitment to IHR obligations would have strengthened preparedness, international cooperation, and timely notifications of public health events, which could have provided more meaningful alerts and improved the early response against an emerging pathogen with pandemic potential. Furthermore, one of the key recommendations made by the Committee, which went along with the results reported in this assessment, was for the ‘integration of the core capacities for emergency preparedness, surveillance and response within the broader health system and essential public health functions, in order to ensure that national healthcare systems are resilient enough to function effectively during pandemics and other health emergencies.’¹⁶

On the other hand, it is important to highlight the preparedness (Core capacity 5) and laboratory components (Core capacity 8), which were classified as level 3 and were, therefore, the strongest capacities in Portugal. Nevertheless, Portugal had the highest number of daily confirmed deaths from COVID-19 per million in January 2021. This points to the insufficiency of these core capacities alone in ensuring an adequate response.

The laboratory component was a perfect example of

what can go well, especially in its multidisciplinary approach with the involvement of all stakeholders in decision-making. The interoperability and cohesion between DGS and INSA made it possible to set up a diagnostic network that constituted one of the country's strongest points and was integrated into the European network.

Possible limitations of this study are worth noting. First, although the analysis was carried out through an extensive literature review complemented by the experience of front-line health workers, there may well be classified documents, whose access could potentially change the level attributed to each IHR core capacity. Nevertheless, the lack of publicly available information reflects non-compliance with the IHR. Second, the 16-month gap between this analysis and the declaration of a pandemic in March 2020 by the WHO may have positively influenced personal interpretations of core capacities, even though this bias was dealt with by collecting and reflecting on the same data.

This country-level evaluation of IHR implementation during the COVID-19 pandemic showed that the IHR might not be able to single-handedly assess a country's capacity to deal with PHEIC. The IHR provide a good theoretical foundation, but the WHO must engage with the member states individually to improve their compliance especially when it comes to developing supplementary tools to facilitate their implementation, progress monitoring, and evaluation of potential changes and future needs.

With an established public, national healthcare system and long-running surveillance strategies, we believe that Portugal's scale and organization can provide a unique background to analyze health policy implementation during public health emergencies. By testing how the IHR and its assessment tools, as the checklist for monitoring its progress, performed in this context we aimed to contribute to more robust, resilient, and effective IHR.

CONCLUSION

In short, this study highlights the need for greater focus on preparation, prevention, and training instead of a predominantly reactive response, which may incur greater costs and health and economic risks of future PHEIC. The IHR are imperative in any public health emergency, but the COVID-19 pandemic has uncovered great difficulties in ensuring the implementation of several of its core capabilities.

The gaps identified in Portugal show that there is a need to harmonize and strengthen global response mechanisms in public health emergencies. Such responses must be co-

ordinated, adopted early, effective, and universal to ensure the implementation of similar measures required by the IHR. There is a need for greater political, institutional, and financial support to the IHR so that better preparedness can improve national-level responses.

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AUTHOR CONTRIBUTIONS

GQ, JM, FG, JCX, CC: Data collection and interpretation, drafting and critical review of the article.

SCP, PPF, JRo, DS: Data collection and interpretation, drafting of the article.

JC, JRa, JPT, LO: Data collection and interpretation, critical review of the article.

JG, CL: Data collection and interpretation.

TC: Conceptualization of the study, critical review of the article.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

JRo is the vice-president of Associação Nacional de Fibrose Quística.

The authors have declared that no competing interests exist.

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