International Health Regulations and COVID-19 pandemic, challenges and gaps

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Summary
International Health Regulations 2005 contributed to the development of public health emergency control programs of international concern. The aim of their application was to mitigate the effects of the spread of such emergencies by proactive measures, stemming from risk assessment and expanding to epidemiological modeling systems that allow a logical extrapolation of what these emergencies can cause, and develop codified international strategies to avoid the occurrence of public health emergencies of international concern as soon as they are early discovered. The COVID-19 pandemic came to be a model in which these regulations were tested in the biggest challenge that human societies have faced since the Second World War. The implementation of these IHR 2005 had a great positive role in limiting the spread of the disease, but some gaps, that could have been overcome and mitigate its consequences, appeared during the application of the precautionary economic, social and health quarantine systems. This study examines the importance of IHR 2005 and the main challenges it faced in general, focusing on the results of their application in the area of the COVID-19 pandemic and the gaps that have emerged in the technical, educational and political field and proposals to address them.

Introduction

International Health Regulations (IHR 2005) are a set of legally binding regulations for all World Health Organization (WHO) Member States. They aim to harmonize the protection of public health while avoiding unnecessary disruption of trade and travel through the development of effective global alert, surveillance and response strategies for all priority public health events.

The IHR (1969) have been used by WHO Member States to guide international prevention and control of infectious diseases until June 2007. The IHR (1969) obliged WHO Member States to notify the WHO of cholera, plague and yellow fever outbreaks in their territories. In addition, the IHR (1969) included requirements for health and vaccination certificates for travelers from infected to non-infected areas; rerating, disinfecting and disinsecting of ships and aircraft; as well as detailed health measures at airports and seaports in the territories of WHO Member States.

In view of the increased risks resulting from various health conditions that cause anxiety at the international level, the IHR were developed in 2005 for approval by the health ministers in the member states at the 2007 General Assembly meeting of the WHO and their implementation starts from that date. Contributing to this is that globalization has made national and geographical borders increasingly porous from pathogens, and therefore the fight against infectious diseases requires international cooperation and coordination, and this became more evident when the new COVID-19 virus appeared in 2019, providing a strong rationale for global public health management.

Among the factors that contributed to the review of the IHR are the emergence of the SARS epidemic in 2003 and 2 other important challenges that impeded the implementation of the IHR 2005 are the suspension of polio vaccinations in northern Nigeria and Indonesia's refusal to exchange samples of H5N1 influenza viruses collected in this country with the WHO.

The effective implementation of the 2005 IHR requires overcoming technical, resource, governance, legal, and political challenges.

The main challenges facing IHR in the twenty-first century

Since 2009 there have been six public health emergencies of international concern (PHEIC) declarations, the 2009 H1N1 (or swine flu) pandemic, the 2014 polio declaration, the 2014 outbreak of Ebola in Western Africa, the 2015-2016 Zika virus epidemic, the ongoing 2018-2020 Kivu Ebola epidemic, and the ongoing COVID-19 pandemic, which was declared a PHEIC on 30 January 2020.

Emerging infectious diseases often create technical challenges for implementing the International Health Regulations, even in the most technologically advanced and well-resourced countries. New emerging pathogens present themselves in unusual or unexpected ways. Modern modeling shows that the ability to control the spread of new pathogens is influenced by the transmission rate that occurs before the onset of symptoms or through an asymptomatic infection. This characteristic explains why diseases such as influenza and HIV are more difficult to control than smallpox or SARS. Improved diagnostic techniques may help public health authorities to identify pathogenic threats and build strategies to enhance reporting processes.

Resource challenges

The requirements of the IHR 2005 challenges will face many countries, especially developing countries, with resource challenges. The IHR 2005 do not include funding mechanisms, which makes each State party bear the financial costs of improving its domestic, intermediate, and national capacities.

Governance challenges

Governance challenges include administrative and managerial weaknesses in countries from the local to the national level. Only a few countries have assessed their ability to detect and respond to disease threats.

Legal challenges

States parties face legal complications in implementing the IHR 2005 within their national legal and constitutional systems.

Political challenges

The level of political commitments of different countries will demonstrate different challenges in implementing the IHR 2005.

Although the IHR 2005 contain some provisions that directly address these challenges, active support from the WHO and its member states is required to strengthen national and global capacities to understand the goal of developing and implementing such regulations.

The most exciting measure under the IHR 2005 is the announcement of a 'Public Health Emergency of International Concern' and the consequent adoption of limited-term 'interim recommendations' for urgent measures to contain the spread of any new pathogen with global concern locally and internationally. The advertising standards for PHEIC focus on serious, unusual or unexpected events that have public health effects outside the borders of the affected country and may require immediate international action.

IHR and the Global Health System

Global healthcare spending slowed to 3.2 percent in 2019, from 5.2 percent in 2018. This is the impact of currency shifts and slowing global economic growth caused by geopolitical tensions, including the trade war between the United States and China and the trade war between the UK to plan Out of the European Union. However, health spending expected to increase during the period 2019-2023 with a more robust Compound Annual Growth Rate (CAGR) of 5 percent, compared to 2.7 percent in 2014-2018. All regions except North America expected to see accelerated average spending growth in the forecast period, with the largest annual increases in the Middle East / Africa (7.4 percent) and in Asia (7.1 percent).

Likewise, global healthcare spending as a share of GDP is likely to remain at around 10.2 percent until 2023, which is equivalent to 2018. This projected steady state reflects economic improvements and health systems efforts to contain costs.

On a per capita basis, spending is likely to continue to spread unevenly, from $ 12,262 in the United States to only $ 45 in Pakistan in 2023. High population growth in many developing economies will hamper efforts to bridge this gap.

With a world population of 7.7 billion in 2019 to reach 8.5 billion by 2030, meeting health needs will not be easy. However, Asian countries are also likely to contribute about half of the global growth in high-income families (those that earn more than US $ 25,000 annually). Population growth, along with increased economic strength and efforts to expand public health systems, are likely to increase spending on health.

Providing health care for an increasing aging demography is a major concern for governments and health systems. Moreover, the life expectancy will rise from 73.7 years in 2018 to 74.7 years by

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2023. The number of people over the age of 65 will exceed 686 million, or 11.8 percent of the total population. This trend will be more pronounced in Japan, where the proportion of people over 65 year old is expected to reach nearly 29 percent by 2023; in Western Europe, the proportion is expected to reach 22%. Therefore, spending on the global aged care market (home health, remote patient monitoring, etc.) is likely to exceed $ 1.4 trillion by 2023. Dementia currently affects more than 50 million people aged 60 years and over globally. The figure expected to reach 82 million by 2030 and 152 million by 2050. While communicable diseases remain a threat, especially in developing countries, chronic and non-communicable diseases are also increasing. Almost 425 million people were diabetic in 2017. By 2045, this number expected to rise 48 percent to 629 million. China (114.4 million), India (72.9 million), and the United States (30.2 million) topped the list of people with diabetes in 2017 and expected to maintain these proportions until 2045. Despite the development of medical technologies, lifestyle factors including smoking, poor nutrition, high blood pressure, obesity, and lack of physical activity remain and contribute to the top ten causes of death. Often this human group is more likely affected by the disease pandemics, because most of them suffer from many stubborn and chronic diseases starting from cardiovascular injuries, through chronic respiratory diseases, diabetes, tumors, high blood pressure, etc., and thus their health systems will be unable to meet the needs of treatment and recovery of patients.

IHR 2005 represent a major development in the use of international law for public health purposes. One of the most important aspects of IHR 2005 is the establishment of a global surveillance system for public health emergencies of international concern.

Through these regulations, public health surveillance defined as "the ongoing systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice". A surveillance system requires structures and processes to support these ongoing functions.

The surveillance system includes four main elements: 1) health-related events under surveillance and their public health importance, 2) purpose and objectives of the system, 3) components and processes of the system, and 4) resources needed to operate it.

IHR 2005 remain a valuable but potential framework within which to address infectious diseases across international borders. Another challenge to IHR 2005 implementation involves its requirement for significant public health capacity building, particularly with regard to infectious disease surveillance.

IHR 2005 identify health-related events that each country that agrees to bind by the regulations must report to WHO. In terms of health-related events that occur in its territory, a state party must notify WHO of "all events which may constitute a public health emergency of international concern". These events include any unexpected or unusual public health event regardless of its origin or source. IHR 2005 also require state parties, as far as is practicable, to inform WHO of public health risks identified outside their territories that may cause international disease spread, as manifested by exported or imported human cases, vectors that may carry infection or contamination, or contaminated goods.

IHR 2005 contain a 'decision instrument' that helps state parties identify whether a health-related event may constitute a PHEIC and therefore requires formal notification to WHO. The decision instrument focuses on risk assessment criteria of public health importance, including the seriousness of the public health impact and the likelihood of international spread.

IHR and COVID-19

The COVID-2019 is a persistent global disease caused by novel Corona Virus (SARS-CoV-2). The outbreak began in Wuhan, Hubei Province, China, in December 2019. The WHO announced that the outbreak was a public health emergency of international concern on January 30, 2020, and it was recognized as a pandemic on March 11, 2020. Until February 9, 2021, there were nearly 107,101,319 cases reported in 213 countries and territories, resulting in approximately 2,338,961 deaths. About 78,980,813 people recovered.

In contrast to the SARS outbreak in 2003, China demonstrated greater transparency in communication on a daily basis for its epidemiological situation, early participated in the genomic sequencing of the virus in an open-access database, accepted the presence of the WHO support team, and took strict control measures including quarantine for millions in Wuhan and other cities. The WHO has established itself as a central institutional center in this case, providing guidance and assistance, coordinating research on vaccines, diagnostics and antiviral drugs, and framing the international response on standard terms under the International Health Regulations.

In order to achieve these regulations, countries must achieve a set of basic capabilities in their national health systems in order to immediately detect report and respond to public health risks and emergencies. This has proven to be one of the major implementation challenges as the IHR lack a dedicated funding mechanism and a formal

compliance monitoring mechanism. Partially, many of these countries are still far from achieving the required capacities. Problems and uncertainties also arise regarding the coordination of the international response to PHEIC, and the outbreak of COVID-19 underscores these challenges.

While the IHR 2005 contain relatively clear obligations regarding due diligence and cooperation in addition to general and routine health measures, national measures in response to the PHEIC standard are meant to be guided by WHO's interim recommendations. However, the available practice shows an inconsistent level of compliance, especially with regard to restrictions on travel and trade with the affected countries.

The current COVID-19 outbreak tests again the effectiveness and credibility of the IHR 2005 not only as a legal tool but also as a public health tool and framework for guiding narrative political challenges, sovereignty tensions, economic interests and national security considerations.

There are serious design and implementation questions that must be addressed urgently to avoid the irreversibility of the IHR 2005 as the only legal framework indispensable to global health security.

The COVID-19 pandemic caused an escalation in the number of victims and a collapse in the global economy. It has emerged as a basic test for political leaders. Although there are conflicting views about the ability of national political leaders to advance or stand powerless behind a 'curve' of rapidly changing dynamics. They are clearly striving to take decisive decisions in controlling health systems in their countries. But they lack data that enable them to actually know the number of people who will be infected, the number of people who will die from this disease, the number of patients who will overwhelm hospitals the more the disease spreads, and how the economic infrastructure of the state could be threatened by such a pandemic.

IHR gaps for COVID-19

Countries differed significantly in their ability to prevent, detect and control outbreaks, with about half of countries reporting operational readiness capabilities to respond to public health emergencies.

Several factors affect the emergence and spread of infectious disease outbreaks within countries and between regions, including the strength of the capacity of the IHR at the national and local levels, adherence to infection prevention and control measures, climate pressures, and population density. The analyses of the operational readiness index have used to support the development of a draft WHO strategic preparedness and response plan for COVID-19. These findings must triangulated with the latest risk assessments available for COVID-19 and other assessments such as Joint External Evaluations, after-action reviews, simulation exercises, and others to understand the capacity level of countries and to implement priority actions at the national and local levels. The WHO Secretariat is working on the development of a preparedness dashboard to provide real-time information that based on these capacity assessments. Another limitation related to the method based on a deterministic approach; therefore, proportionate or inverse interactions among variables not shown.

An effective way of managing airborne infections is applying evidence-based public health prevention strategies. This method includes scaling up public awareness of behaviors such as hand hygiene and respiratory etiquette, communicating and engaging with local communities about the risks of the outbreak, and putting in place effective public health response measures. National points of entry should also have the capacity to prevent, detect, and respond to potential threats in line with the IHR. Many countries have low capacities for preventing the occurrence and spread of outbreaks, such as measles, influenza, Ebola virus. Therefore, enhancing national preparedness capacities in line with the gaps identified in this study should incorporate action to strengthen points of entry.

Many countries have made substantial progress in developing effective levels of disease detection, which involves strengthening surveillance and laboratory capacities. The application of lessons learned from previous infectious disease emergencies including the 2002 SARS-CoV, 2009 H1N1 influenza pandemic, MERS-CoV, Ebola virus, and Zika virus outbreaks, have helped to strengthen countries' capacities to effectively detect and verify suspect cases. The early detection of COVID-19 in China and the development of laboratory reagents for testing and genetically sequencing the novel virus are key steps that have supported the early response. Seventy six percent of countries have robust detection capacities in place, which enable early detection and verification of potential outbreaks when they occur.

Mutations accumulating during epidemics increase the replication fitness of the virus in cell culture and increase virulence in an animal model. The Phylogenetic tree has a coalescence center with exponential expansion identified by haplotype markers. The color-mapped phylogenies largely support the 14 identified sub clades. The substantial numbers of samples from the United States show affinity with European lineages rather than those directly derived from East Asia. Except for the earliest cases, European clades dominate even in samples

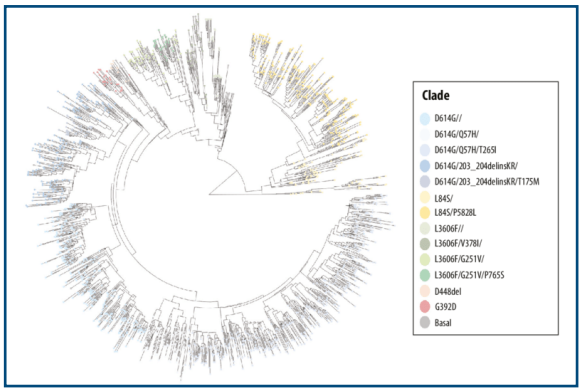

Figure 1. *Phylogenetic tree for the SARS-CoV-2 genomes, 2019-2020.*

from western states in the United States. Further, European samples tend to associate with lineages that expanded through Australia. Estimation of mutation rate showed a median of 1.12 × 10-3 mutations per site-year (95% confidence interval, CI: 9.86 × 10-4 to 1.85 × 10-4). The median tree height was 5.1 months (95% CI: 4.8 to 5.52)

Mutations in the receptor-binding domain of the spike protein suggest that these variants are unlikely to reduce binding affinity with ACE2. V483A and G476S are primarily observed in samples from the United States, whereas V367F is found in samples from China, Hong Kong Special Administrative Region, France and the Netherlands. The V367F and D364Y variants have been reported to enhance the structural stability of the spike protein facilitating more efficient binding to the ACE2 receptor.

The ability to respond in a country depends on the strength of its preparedness for emergencies, the rapid testing of its causes and risk factors, and the regular updating of national plans and capacities. An effective response to an outbreak depends not only on the availability of adequate human resources and funding, but also on the ability to manage emergency logistics services (including handling supply chains for essential products needed during an emergency). The results that emerged while dealing with the COVID-19 pandemic show that many countries need support to achieve these capabilities, and more support should be provided as a global priority action to enhance health security. It was found that operational readiness capabilities and enabling functionality were low in many low-resource countries, and this necessitated the need for increased investment in strengthening the capacities of IHR. It also showed the low national preparedness capabilities due to insufficient investment in human capital and weak planning for continuity in support of combating the spread of infectious diseases.

Perhaps the greatest challenge facing the IHR in addressing new pandemics is the careless to early investigation of potential situations that can threaten people as a result of changing patterns of life associated with climate change, human-animal interaction, sustainable life-threatening problems such as hunger, poverty, pollution, and declining quality of education and others. IHR could not yet been able to apply the concept of 'One Health' in dealing with emerging and re-emerging diseases, which has delay the response to such pandemics. In addition, the irresponsible political response in all different aspects caused delayed disease control operations and the emergence of severe economic and social effects on all societies in a way in which the success stories of applying early warning and reassuring response systems to people turned into indicators of horror and severe anxieties. The problems of stopping production, education and movement between countries have catastrophically led to the transformation of health education processes towards diseases into political platforms for the exchange of accusations, and a space for settling scores between countries.

Public health education (PHE), ignoring the concept of 'One Health' and their impact on the future aspects of the IHR

Public health competencies, especially with regard to managing epidemic and chronic diseases, are of increasing importance for the global workforce in the healthcare field. It is necessary to strengthen public health education and related disciplines in basic medical education. It also became evident during the COVID-19 pandemic that developing guiding goals that should support the development of university medical education in the areas of public health and considering it a basic requirement has become necessary. The progress of university medical education in the field of public health is also a global challenge to answer a set of questions that include: what we learn in PHE? How do we learn PHE? When do we learn PHE? Why do we learn PHE? Evidence-based health care has re-emerged the importance of clinical epidemiology, considering PHE a pursuit of postgraduate studies.

Therefore, the available risk assessments should developed for any pathogen from all animal and environmental sources that can threaten human health and link them with other assessments to understand current capabilities and their implications for people's lives and the development of societies. The World Health Organization is working to develop a preparedness dashboard (a data visualization platform that will include a query system) to provide information in real time, and in a virtually based manner on various capacity

assessments, taking into account the commitment to health studies in the field of veterinary medicine, as a basis for assessing the epidemiological situation, and improving national, regional and global surveillance system based on the concept of one health. It has become clear that despite the gains in understanding the pathogen, many countries are unwilling to manage cases within their borders. Their health systems were therefore unsuccessful. Investments in preparedness should urgently increase to ensure that vulnerable countries are operational, and able to respond to public health events such as the outbreak of COVID-19.

Future requirements for the development of IHR

One of the most important challenges faced by humankind in the twenty-first century is the experience of dealing with the COVID-19 pandemic. The international community has demonstrated its ability to benefit from international laws in controlling the spread of epidemics and limiting the spread of epidemics in an unprecedented manner. International political differences have not stopped an obstacle for health authorities to impose a global health system that all countries adhere to without exception and implemented popularly at all levels.

All countries of the world benefited from the application of IHR, and were able to draw the world's attention to the dynamics of disease development in a real and direct way. They participate effectively in the processes of controlling it.

During the implementation of the IHR, some weaknesses that could overcome to mitigate more than the effects of the direct and indirect pandemic highlighted. Among these points:

1. Lack of strict international rules to ensure the availability of basic prevention elements in all countries, providing the minimum necessary to secure adequate databases for early detection of pathogens that may have international concern (epidemiological surveillance programs, intersectoral cooperation, regional and international coordination, effective programs for public health education in medical higher education).
2. The inability of political systems to hand over the affairs of the integrated health management in the country during crises and disasters to specialists to reduce the problems of issuing irresponsible decisions that can increase the problem rather than get rid of it.
3. Failure to apply the concept of "One Health" in implementing IHR, delaying early detection of pathogens of international importance and making control of them start from the beginning of the emergence of disease cases, so that most of the measures taken can stop the spread of the pandemic instead of limiting its occurrence.
4. The inability of IHR to define a well-informed health reporting and awareness system, and leave plenty of false ideas and information to spread among people and influence the course of control programs.
5. The thoughtlessness of IHR to place control measures for local infection foci's for pathogens that have not yet come into international concern, so that international outbreaks and pandemics can occur. It is necessary to include in these regulations the rules of epidemiological outbreak investigation and methods of implementing quarantine of infection foci's.

Conclusions

IHR 2005 harmonize the protection of public health and avoid unnecessary disruption of trade and travel through the development of effective global alert, surveillance and response strategies for all priority public health events.

IHR 2005 contain a 'decision instrument' that helps state parties identify whether a health-related event may constitute a PHEIC and therefore requires formal notification to WHO. The decision instrument focuses on risk assessment criteria of public health importance, including the seriousness of the public health impact and the likelihood of international spread.

The current COVID-19 outbreak tests again the effectiveness and credibility of the IHR 2005 not only as a legal tool but also as a public health tool and framework for guiding narrative political challenges, sovereignty tensions, economic interests and national security considerations.

The COVID-19 pandemic caused an escalation in the number of victims and a collapse in the global economy. It has emerged as a basic test for political leaders.

Several factors affect the emergence and spread of infectious disease outbreaks within countries and between regions, including the strength of the capacity of the IHR at the national and local levels, adherence to infection prevention and control measures, climate pressures, and population density.

During the implementation of IHR procedures in the control of COVID-19 pandemic, some weaknesses that could overcome to mitigate more than the effects of the direct and indirect pandemic has been highlighted in this paper as a challenge for the future development of IHR.

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