



Legal and Regulatory Frameworks for International Health Data Sharing: A Comprehensive Review of Cross-Border Health Data Management During Pandemics

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Abstract

Background: In recent decades, the global health landscape has been increasingly challenged by pandemics, underscoring the need for effective cross-border health data sharing. The COVID-19 pandemic exemplifies how interconnectedness can facilitate the rapid spread of infectious diseases, necessitating robust legal and regulatory frameworks to manage health data across borders. This narrative review synthesizes the current literature on the legal and regulatory challenges associated with international health data sharing.

Methods: We conducted a comprehensive evaluation of published studies, governmental reports, and guidelines from reputable sources, including PubMed, Scopus, and WHO documentation, focusing on the last four years. Our analysis reveals significant disparities in vaccination access, approval processes, and technological infrastructure among countries, which complicate the global implementation of Digital Health Passports (DHPs).

Results: Key findings indicate that inequitable vaccine distribution, varying regulatory standards, and digital divides hinder the effectiveness of DHPs in pandemic management. Furthermore, our review highlights the necessity for international cooperation to establish harmonized regulatory standards and practices that safeguard individual privacy while facilitating data sharing.

Conclusions: In conclusion, addressing the geographical and operational barriers to effective health data sharing is crucial for enhancing global pandemic response strategies. The findings underscore the

importance of developing flexible and adaptive frameworks that can effectively respond to future health crises. Collaborative efforts among governments, international organizations, and technology providers are essential to overcoming existing challenges and ensuring equitable access to health data across borders.

Keywords: Cross-border health data sharing, pandemic management, Digital Health Passports, regulatory frameworks, vaccine equity.

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1. Introduction

In recent decades, the incidence and intensity of pandemics impacting millions worldwide have markedly escalated. Despite recent substantial progress in science and medicine, the likelihood of infectious illnesses spreading is rising, along with the chance of outbreaks escalating into epidemics or pandemics [1]. Multiple reasons contribute to this trend, including heightened globalization and connectivity, which enable disease pathogens to disseminate rapidly throughout the globe, sometimes within hours [2]. The COVID-19 pandemic exemplifies how epidemics may impact millions globally. The COVID-19 pandemic challenged health systems and adversely affected the worldwide community's social and economic conditions. The transport and tourist industries suffered significantly due to national governments' implementation of stringent containment measures to curb the virus's spread. These measures included travel restrictions, prohibitions on social gatherings, home confinement, and quarantines [3,4]. To alleviate the repercussions of these control measures, individuals needed to be securely reintegrated into the impacted social and economic activities. This included gathering data on an individual's health condition, including recent negative COVID-19 test results, and subsequently, when vaccines became accessible, vaccination mandates, which led to the emergence of COVID-19 digital health passports (DHPs; vaccine passports or certificates) [5,6].

This method is predicated on the premise that not all individuals need quarantine to mitigate the transmission of the illness. Permitting persons with a minimal risk of infection to roam freely may alleviate the strain on the healthcare system and sustain economic activity. The 2005 International Health Regulations (IHR) underscored the importance of protecting international traffic and trade from disruption; however, the COVID-19 pandemic's unparalleled global impact revealed the need to amend the IHR to more effectively address the challenges posed by this health crisis [7]. As a result, COVID-19 vaccination passports were globally instituted in diverse manners. The European Union (EU) established the EU Digital COVID Certificate (EU DCC), which includes recovery, vaccination, and testing certifications, enabling vaccinated EU persons to travel within the EU [8,9]. International organizations executed efforts; for instance, the International Air Transport Association (IATA) introduced the IATA Travel Pass, primarily used by airlines to authenticate COVID-19 test results and digital vaccination certificates. Private enterprises also participated; for example, IBM created the IBM Digital Health Pass, used blockchain technology to authenticate health credentials in a decentralized manner, so guaranteeing that only those who satisfied certain health criteria were permitted entry to the premises [10,11].

The efficacy of vaccination has led to a substantial reduction in daily reported cases, prompting several governments to relax their formerly harsh requirements. Nonetheless, the risk of infection persists, accompanied by the potential formation of more transmissible variations [12]. Epidemiologists warn that climate change, habitat degradation, and heightened human-animal interaction substantially elevate the danger of future pandemics by enhancing the likelihood of zoonotic spillover [13]. Coronaviruses and influenza viruses provide a significant concern owing to their fast development, high transmissibility via respiratory droplets, and zoonotic transmission. These viruses, originating from natural reservoirs in both domestic and wild animals, have previously resulted in spillover episodes when the virus transmits from animals to people. Such phenomena may persist in the future. Their genetic variety and adaptability make them potential reservoirs for novel zoonotic diseases, since the viruses may develop and acclimatize to new hosts [14]. Initiatives like the Global Virome Project, which aims to identify potential viral threats, and the Coalition for Epidemic Preparedness Innovation, which secures funding for vaccine pipeline development to address future pandemics, present promising opportunities for substantially shortening the vaccine

development timeline. This indicates that DHPs are likely to play a significant role in future pandemics as well. Consequently, traversing the post-COVID-19 landscape necessitates a robust system that is sensitive to evolving health concerns and adaptive to distinct circumstances across various global regions [15-18]. The COVID-19 pandemic has resulted in inequities and varied techniques across nations in their responses, often influenced by socioeconomic circumstances and advancing scientific knowledge, hence presenting significant hurdles to the proper functioning of DHPs [19].

This narrative study outlines the geographical and practical obstacles to the worldwide application of DHPs for pandemic management. We propose a framework for potential solutions and offer insights into the diverse tools and strategies that stakeholders, such as governments, international organizations, and technology providers, can utilize to address the geographical complexities and practical challenges linked to the global implementation of DHPs. This work advances the creation of flexible and adaptive DHP solutions that can successfully tackle distinct global challenges and react to present and upcoming health hazards globally.

2. Methods

We performed a narrative evaluation of the published literature, websites, and other internet resources to gather data from the last four years. Our sources were PubMed, Medline, Google, Scopus, Google Scholar, and other online sites, including those from the WHO.

3. Diverse vaccination landscape: inequities in access and diversity in regulation

The current availability of COVID-19 vaccinations has markedly increased, considerably alleviating the supply limitations faced earlier in the epidemic. In the case of a pandemic such as COVID-19, marked by fast worldwide transmission, the demand for vaccinations may exceed the available supply. The fast mutation and development of the virus add another degree of complexity, since new variations may need adjusted or booster doses, hence complicating the vaccine supply-demand dynamic. The intricacies of vaccine delivery within a rapidly proliferating epidemic are fundamentally complicated. It is essential to examine the complex relationship among the velocity of vaccine discovery, manufacturing capabilities, cost-effectiveness, and accessibility, which mostly advantages industrialized nations. Furthermore, the interaction of elements such as population density, healthcare infrastructure, and vaccine reluctance add further complexities to this matter [20]. These issues are intensified in places afflicted by conflict and violence, since such circumstances severely impact medical infrastructure and supply networks, resulting in increased vulnerability relative to areas devoid of such conflicts or wars [21]. Furthermore, marginalized populations, including economically disadvantaged individuals and racial/ethnic minority groups, have persistently shown less faith in immunization programs and increased mistrust. The distribution of vaccinations across different demographic groups, while accounting for high-risk populations and vital workers, adds additional complexity to the vaccine distribution system [22,23]. Consequently, vaccination passports may exhibit discriminatory tendencies, favoring more developed nations, rich societies, and people at the expense of their less privileged peers and underprivileged populations.

A viable resolution to the vaccine production bottleneck would certainly need the transfer of intellectual property or technical expertise to enhance manufacturing capacity. This may include licensing agreements among pharmaceutical firms, technological transfers, or the formation of joint ventures [24]. By exchanging information and experience, producers across various nations might enhance their manufacturing capacities and facilitate a more equal distribution of vaccines. Upon securing a sufficient supply of vaccinations, governments must establish processes that guarantee justice and equality in vaccine distribution. To achieve equitable vaccination distribution, proper allocation must be established, and vaccine acceptance should be promoted. By collaborating with community volunteers, mobile vaccination teams effectively accessed elderly citizens in secluded villages and rural communities, leading to a positive outcome characterized by a substantial rise in participation in African nations [21]. Advancing equality within and amongst priority groups is crucial to alleviate the widespread impacts of ethnic and socioeconomic inequities present in many institutions. This requires emphasizing historically

disadvantaged populations, illegal immigrants, and the homeless in vaccination distribution and outreach initiatives [25].

Collaborative efforts, such as the COVID-19 Vaccines Global Access (COVAX) facility, might be crucial in mitigating global vaccine disparities by enabling the fair distribution of vaccines to low- and middle-income countries (LMICs). COVAX is an effort financed by industrialized nations, international organizations, and charitable groups, all aimed at ensuring that vaccinations are accessible to the most vulnerable people [26]. Furthermore, low- and middle-income countries should contemplate augmenting investments to fortify and improve their health and cold chain infrastructure, maybe with assistance from the global community. This initiative should include the investigation of solar-powered refrigeration solutions in areas with inconsistent or disrupted electrical supplies [27]. These facilities are essential for the efficient delivery of vaccinations and for overseeing vaccination campaigns, especially in resource-limited environments [28, 29]. During a broad pandemic like COVID-19, community institutions such as churches, mosques, and other public venues, as well as temporary locations like open fields with tents, may function as vaccination stations. This method of leveraging community facilities has traditionally been used to mitigate the deficiencies of medical infrastructure in several African countries while confronting diverse public health issues, including the Ebola epidemics [30]. Utilizing local community facilities as immunization sites may effectively engage persons who may have worries around possible monitoring by authorities [31].

Vaccine hesitancy is a complicated issue influenced by several variables, including personal perspectives, cultural beliefs, disinformation, distrust in healthcare institutions, historical background, and societal pressures. This problem is not uniform; it differs across many cultures and people [32,33]. Mitigating vaccination hesitancy necessitates investments in culturally appropriate and accessible public health programs. These initiatives must provide precise information in local languages, perhaps via reputable community and religious leaders and accessible media channels. These initiatives must prioritize the dispelling of myths and misunderstandings by transparent and empathic dialogue, fostering trust, and emphasizing the significance of vaccination as a means to safeguard both individual health and the communal welfare of the whole population [34]. These initiatives not only enhance public health but also provide a basis for more effective implementation of DHPs in the future.

4. Variable landscape of vaccine authorization and approval

The complex processes of vaccine licensing and approval were underscored by the COVID-19 pandemic. Regulatory bodies globally use diverse review processes and schedules for the licensing or approval of vaccinations. Some authorities accepted data from worldwide clinical trials, while others mandated local clinical trials for vaccination licensure [35]. This prompts relevant inquiries about the validity of vaccinations for DHPs throughout a pandemic. Divergent degrees of vaccination approval across nations might impede the multicountry adoption of DHPs, resulting in considerable obstacles and uncertainty for those intending to use DHPs for foreign travel and other activities. For example, people may face conflicting travel and seclusion mandates. The introduction of SARS-CoV-2 variants of concern (VOC) intensified the challenges associated with the licensing and approval of COVID-19 vaccines. The variations significantly impacted global vaccination choices, with certain nations expressing apprehensions over the efficiency of current vaccines and selecting particular kinds based on their perceived effectiveness against specific variants [36]. In South Africa, the beta (B.1.351) variation prompted the government to choose the Pfizer-BioNtech and Johnson & Johnson vaccines over the Oxford-AstraZeneca vaccine, despite the country's involvement in its trials. The Gamma (P.1) variety raised concerns in Brazil, fostering the perception that the strain exhibited greater resistance to current immunizations [37]. In India, the Delta (B.1.617.2) variation prompted the government to prioritize the distribution of Covishield, a derivative of AstraZeneca, and Covaxin, produced by Bharat Biotech. These preferences modified vaccine distribution patterns and administration tactics across different locations, leading to disparities in access to certain vaccinations, since polymorphisms affected the kinds of vaccines used and authorized in each place. Concerns were expressed over the frequency of vaccination certificate renewals and the potential for passports to be revoked, maybe with little notice.

Various reasons may account for worldwide discrepancies in vaccine regulation guidelines, including data deficiencies regarding vaccine interchangeability, the absence of a universal agreement on acceptable clinical trial criteria, political influences shaping public perception, and geostrategic concerns [38]. Interchangeability, defined as the capacity to use several vaccinations in differing dosages or schedules to attain equivalent protection, presents a considerable obstacle to establishing worldwide agreement and mutual acceptance of these vaccines [39]. Furthermore, there is an absence of international agreement about the criteria for permissible human clinical studies [40]. Different regulatory authorities may have various criteria and procedures for evaluating the safety and effectiveness of vaccinations [41]. Variations in recommendations may stem from divergent scientific viewpoints, technological progress, the ability to do clinical trials, and the interpretation of existing evidence [40]. Additionally, political factors significantly influence public perception and regulatory choices about vaccinations. While governments and officials often emphasize public health and safety, they may also encounter pressure to reconcile domestic politics, public trust, and national economic interests. Consequently, these political factors may affect the pace of vaccine approval, the degree of openness in decision-making, and the communication of the risks and advantages of particular vaccinations to the public [42, 43]. Moreover, geostrategic factors, especially among affluent nations, may affect regulatory choices. A complicated interaction occurs between vaccine development and distribution and both national and international interests. As a result, nations may endeavor to ensure adequate vaccine supplies for their citizens while attempting to acquire or sustain influence in global health diplomacy, potentially resulting in differing levels of urgency regarding specific vaccine authorizations, approvals, and prioritization within regulatory frameworks [44].

Consequently, addressing the inconsistencies in vaccination authorization procedures within these issues necessitates a comprehensive strategy. This methodology entails establishing scientific agreement via international cooperation, political initiatives, and the use of technology [45]. Recent initiatives have concentrated on harmonizing technical requirements for the registration of pharmaceutical and medical device products via the International Council for Harmonization, leading to the establishment of widely accepted global guidelines; however, these efforts have not been extended to the regulatory review processes. The hurdles faced during crises like the COVID-19 pandemic and other recent outbreaks, including severe acute respiratory syndrome, Middle East respiratory syndrome, Ebola, and Zika, have highlighted the complexities of coordinating international regulatory responses [46].

To attain a more cohesive strategy for vaccine authorization, scientific collaborations that encompass the sharing of clinical trial data, the standardization of research protocols, and the facilitation of transparent scientific discourse concerning vaccine authorization and approval processes among pertinent stakeholders can enhance the evidence base for vaccine efficacy and safety. Previous epidemics, including Ebola, demonstrated that a collaborative strategy, exemplified by the African Vaccine Regulatory Forum, significantly enhanced the efficacy and advancement of regulatory procedures pertinent to Ebola vaccine research [46]. International institutions, like the WHO, can effectively coordinate collaborative efforts across nations for convergence and mutual recognition. This will significantly facilitate the acceptance and validation of vaccines permitted by various regulatory agencies by diminishing the need for redundant required vaccine evaluations, which is essential for conserving time and resources during pandemics. Furthermore, to assure the safety and effectiveness of vaccines that have received approval, it is essential to establish a comprehensive post-authorization monitoring system for real-time data collection on adverse events and vaccination performance. This is crucial for vaccine updates when variations arise that may circumvent vaccination-induced antibodies, hence enhancing public trust in vaccines [47].

5. Technological infrastructure and accessibility challenges

The COVID-19 pandemic highlighted the persisting inequalities in access to digital technology between rich and underdeveloped nations. Countries having enhanced technological access effectively used it to mitigate the virus's spread. Developed nations might use technology to track people who have been in touch with the virus, advise them of their potential exposure, and provide them with precise, real-time information about the pandemic and local legislation. Nevertheless, most developing nations, owing to insufficient technical resources, were unable of leveraging these technological developments [48, 49]. Moreover,

although affluent nations rapidly adapted to distant employment and online education, many developing countries struggled with inadequate internet access and deficient digital infrastructure [50]. DHPs need a resilient and reliable digital infrastructure, including secure databases, internet connectivity, and technological devices like as smartphones and PCs. Implementing these components may be more difficult in LMICs with inadequate digital infrastructure or significant gaps in access to digital technologies. Moreover, even in industrialized countries with extensive smartphone use, some demographic groups, such as the elderly, may demonstrate hesitance or incapacity to utilize cellphones [51]. Thus, in addition to lacking access to essential resources and remedies, individuals impacted by the digital divide may be unable to use DHP systems to verify their immunization or testing status, thus increasing their vulnerability during health emergencies.

The availability and accessibility of digital technology may range significantly between various nations, regions, and even within communities in the same nation. Sociodemographic characteristics, including age, disability, education level, gender, and income, significantly influence an individual's access to digital technology globally. Furthermore, unauthorized immigrants facing heightened monitoring and surveillance often have difficulties in using digital technologies owing to the need of presenting identity credentials. Therefore, tackling these difficulties requires a comprehensive strategy that includes offering alternatives, enhancing infrastructure, and facilitating more access to digital technologies [52].

For persons who are entirely unable to access the internet or digital devices for using DHPs, offline options may be considered. These options may provide people with concrete evidence of their health state without depending on digital infrastructure. Two viable offline alternatives are physical cards including a printed barcode or a distinct QR code for each certificate, or an electronic health information card embedded with a microchip [53, 54]. Nonetheless, the execution of these offline options requires careful evaluation of several elements. Mitigating falsifications or counterfeits is vital. Moreover, robust security protocols must be implemented to safeguard sensitive personal information contained on the cards or inside the microchips. Additionally, provisions for various local languages should be made to cater to varied people.

Integrating SMS and USSD services allows individuals without smartphones to get DHP information and services via text messages on their basic mobile phones [55]. Furthermore, investigating the advancement of DHPs with offline functionalities may guarantee that customers may get essential information and services, particularly in regions with intermittent internet connection [56]. DHP interfaces must promote simplicity and user-friendliness to accommodate those with minimal digital literacy, including clear directions and simple navigation [57]. A judicious strategy for these projects is to initiate pilot programs, which enable the discovery and rectification of issues prior to expanding the program to include whole towns or nations.

Although offline alternatives may provide a provisional remedy for those lacking access to digital platforms, a thorough and sustainable resolution to the digital divide must unequivocally include initiatives designed to guarantee equitable access to digital technology for all demographics. This may be accomplished via collaborations and robust regulatory frameworks aimed at tackling the distinct issues posed by the fluctuating digital ecosystem, including expenses and insufficient skills training. Policies must include strategies to ensure digital services are accessible to all users, particularly those in distant or rural regions. This can be accomplished by investing in digital infrastructure development, including dependable internet access and mobile networks, enhancing electricity availability, and partnering with both local and international technology firms to create economical solutions customized to the unique requirements of each nation. Moreover, investing in digital literacy initiatives and conveying the advantages of digital gadgets to the public motivates individuals, particularly those with less technological proficiency, to use them [58]. equal access to digital technology has extensive advantages beyond health passports, as it may improve the efficacy of managing future pandemics and facilitate more equal and efficient crisis response.

6. Operational obstacles in the implementation of digital health passports

The execution of DHPs for pandemic management has several practical difficulties. Vaccination has demonstrated significant efficacy in diminishing the incidence and severity of COVID-19 infections;

however, some individuals may be unable to receive vaccinations or complete the recommended regimen due to medical contraindications related to allergies to specific vaccine components, such as polyethylene glycol in mRNA vaccines. Moreover, breakthrough infections may arise even in fully vaccinated people, especially among high-risk populations with comorbidities or among the elderly [59]. Although the likelihood of severe illness, hospitalizations, and mortality is markedly reduced in these instances, the danger of viral transmission to others persists [60]. This underscores the constraints of depending only on immunization status as a condition for DHP issuance. Likewise, natural immunity gained from previous infection demonstrates heterogeneity in both duration and potency, influenced by individual characteristics and the specific pathogen. Research suggests that natural immunity to SARS-CoV-2 correlates with disease severity, since those with more pronounced symptoms have a more robust immune response [61]. Nonetheless, advanced age and chronic diseases might impair the immune response, increasing vulnerability to reinfection, particularly with more transmissible virus strains [62]. Furthermore, evaluating natural immunity poses difficulties, since current antibody tests may not accurately gauge an individual's protection against infection [63]. The intricacies hinder the integration of natural immunity into DHPs.

7. Conclusions

An examination of the geographical and practical constraints encountered by DHPs uncovers the many barriers obstructing their successful worldwide implementation. Mitigating gaps in vaccination accessibility necessitates coordinated initiatives to improve vaccine development, distribution, and adoption. Successfully navigating the varied terrain of vaccine authorization and approval necessitates a comprehensive strategy that includes international cooperation to create uniform guidelines and standards, science diplomacy, the establishment of scientific consensus on clinical trial data and research protocols, and the utilization of technology in the design of DHPs to address diverse vaccine authorization frameworks and the emergence of variants. Reconciling the essential need for health data interchange with the preservation of individual privacy rights demands coordinated policies and widely accepted data protection rules to ensure confidence and adherence. Furthermore, by investigating the capabilities of decentralized technologies, DHP systems may be created to emphasize individual privacy rights while facilitating the unobstructed transmission of information necessary for effective DHPs. Investing in digital infrastructure, including the expansion of internet access and the provision of digital literacy training, together with offering offline DHP alternatives, will facilitate universal access to DHPs. Given the constraints of vaccination, natural immunity, and conventional testing in exclusively assessing infection risk, DHPs should be seen as an integral element of a holistic infection prevention approach. Supplementary measures, including stringent health checks, mask use, social distance, and hand cleanliness, must to be instituted to further reduce the chance of transmission. By using these tactics, stakeholders may together address the obstacles to universally applicable DHP systems for efficient pandemic management. Ongoing study, assessment, and enhancement of DHP systems are essential for maintaining their efficacy and agility in response to emerging public health concerns.

References

1. Marani M, Katul GG, Pan WK, Parolari AJ. Intensity and frequency of extreme novel epidemics. *Proc Natl Acad Sci USA*. 2021;118(35):e2105482118.
2. Haileamlak A. Pandemics will be more frequent. *Ethiop J Health Sci*. 2022;32(2):228.
3. Gössling S, Schweiggart N. Two years of COVID-19 and tourism: what we learned, and what we should have learned. *J Sustain Tour*. 2022;30(4):915–31.
4. Rahman MM, Thill JC. Associations between COVID-19 pandemic, lockdown measures and human mobility: longitudinal evidence from 86 countries. *Int J Environ Res Public Health*. 2022;19(12):7317.
5. Wells CR, Pandey A, Fitzpatrick MC, Crystal WS, Singer BH, Moghadas SM, et al. Quarantine and testing strategies to ameliorate transmission due to travel during the COVID-19 pandemic: a modelling study. *Lancet Reg Health Eur*. 2022;14:100304.

6. Wang B, Ping Y. A comparative analysis of COVID-19 vaccination certificates in 12 countries/regions around the world: rationalising health policies for international travel and domestic social activities during the pandemic. *Health Policy*. 2022;126(8):755–62.
7. Wilson K, Halabi S, Gostin LO. The International Health Regulations (2005), the threat of populism and the COVID-19 pandemic. *Global Health*. 2020;16(1):70.
8. Ash N, Triki N, Waitzberg R. The COVID-19 pandemic posed many dilemmas for policymakers, which sometimes resulted in unprecedented decision-making. *Isr J Health Policy Res*. 2023;12(1):13.
9. Stanimirovic D, Tepej JL. Introduction of the EU digital COVID certificate in Slovenia: technological and process aspects. *Stud Health Technol Inform*. 2022;289:118–22.
10. Drury J, Mao G, John A, Kamal A, Rubin GJ, Stott C, et al. Behavioural responses to COVID-19 health certification: a rapid review. *BMC Public Health*. 2021;21(1):1205.
11. Ortiz-Millán G. COVID-19 health passes: practical and ethical issues. *J Bioeth Inq*. 2023;20(1):125–38.
12. Varghese R, Kumar D, Sharma R. Global threat from novel SARS-CoV-2 variants, BF.7, XBB.1.5, BQ.1, and BQ.1.1: variants of concern? *Hum Cell*. 2023;36(3):1218–21.
13. Thoradeniya T, Jayasinghe S. COVID-19 and future pandemics: a global systems approach and relevance to SDGs. *Global Health*. 2021;17(1):59.
14. Mishra B, Rath S, Mohanty M, Mohapatra PR. The threat of impending pandemics: a proactive approach. *Cureus*. 2023;15(3):e36723.
15. Carroll D, Daszak P, Wolfe ND, Gao GF, Morel CM, Morzaria S, et al. The global virome project. *Science*. 2018;359(6378):872–4.
16. Halabi S, Gostin LO, Aneja K, Nardi F, Gottschalk K, Monahan J. The Coalition for Epidemic Preparedness Innovations (CEPI) and the partnerships of equitable vaccine access. *J Law Med Ethics*. 2023;51(2):234–46.
17. Lazarus JV, Romero D, Kopka CJ, Karim SA, Abu-Raddad LJ, Almeida G, et al. A multinational Delphi consensus to end the COVID-19 public health threat. *Nature*. 2022;611(7935):332–45.
18. Yang J, Han M, Wang L, Wang L, Xu T, Wu L, et al. Relatively rapid evolution rates of SARS-CoV-2 spike gene at the primary stage of massive vaccination. *Biosaf Health*. 2022;4(4):228–33.
19. Kunyenje CA, Chirwa GC, Mboma SM, Ng'ambi W, Mnjowe E, Nkhoma D, et al. COVID-19 vaccine inequity in African low-income countries. *Public Health Front*. 2023;11(8):1087662.
20. Yarlagadda H, Patel MA, Gupta V, Bansal T, Upadhyay S, Shaheen N, et al. COVID-19 vaccine challenges in developing and developed countries. *Cureus*. 2022;14(4):e23951.
21. Ayenigbara IO, Adegboro JS, Ayenigbara GO, Adeleke OR, Olofintuyi OO. Challenges to a successful COVID-19 vaccination program in Africa. *Germes*. 2021;11(3):427–40.
22. Bardosh K, Figueiredo AD, Gur-Arie R, Jamrozik E, Doidge J, Lemmens T, et al. The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good. *BMJ Glob Health*. 2022;7(5):e008684.
23. Tatapudi H, Das R, Das TK. Impact of vaccine prioritization strategies on mitigating COVID-19: an agent-based simulation study using an urban region in the United States. *BMC Med Res Methodol*. 2021;21(1):272.
24. Wouters OJ, Shadlen KC, Salcher-Konrad M, Pollard AJ, Larson HJ, Teerawattananon Y, et al. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. *Lancet*. 2021;397(10278):1023–34.
25. Mukumbang FC. Are asylum seekers, refugees and foreign migrants considered in the COVID-19 vaccine discourse? *BMJ Glob Health*. 2020;5(11): e004085.
26. Jecker NS. Vaccine passports and health disparities: a perilous journey. *J Med Ethics*. 2022;48(12):957–60.
27. Haidari LA, Brown ST, Wedlock P, Connor DL, Spiker M, Lee BY. When are solar refrigerators less costly than on-grid refrigerators: a simulation modeling study. *Vaccine*. 2017;35(17):2224–8.
28. Fahrni ML, Ismail IA, Refi DM, et al. Management of COVID-19 vaccines cold chain logistics: a scoping review. *J Pharm Policy Pract*. 2022;15(1):16.

29. Rutten LJF, Zhu X, Leppin AL, Ridgeway JL, Swift MD, Griffin JM, et al. Evidence-based strategies for clinical organizations to address COVID-19 vaccine hesitancy. *Mayo Clin Proc.* 2021;96(3):699–707.
30. Waya JLL, Ameh D, Mogga JLK, Wamala JF, Olu OO. COVID-19 case management strategies: what are the options for Africa? *Infect Dis Poverty.* 2021;10(1):30.
31. Nanyonjo A, Nelson D, Sayers E, Lall P, Vernon-Wilson E, Tetui M, et al. Community efforts to promote vaccine uptake in a rural setting: a qualitative interview study. *Health Promot Int.* 2023;38(4):daad088.
32. Pires C. Global predictors of COVID-19 vaccine hesitancy: a systematic review. *Vaccines.* 2022;10(8):1349.
33. Ochieng C, Anand S, Mutwiri G, Szafron M, Alphonsus K. Factors associated with COVID-19 vaccine hesitancy among visible minority groups from a global Context: a scoping review. *Vaccines.* 2021;9(12):1445.
34. Kassianos G, Puig-Barberà J, Dinse H, Teufel M, Türeci Ö, Pather S. Addressing COVID-19 vaccine hesitancy. *Drugs Context.* 2022;11:2021–12-3.
35. Francis AI, Ghany S, Gilkes T, Umakanthan S. Review of COVID-19 vaccine subtypes, efficacy and geographical distributions. *Postgrad Med J.* 2022;98(1159):389–94.
36. Irfan N, Chagla Z. In South Africa, a 2-dose Oxford/AZ vaccine did not prevent mild to moderate COVID-19 (cases mainly B.1.351 variant). *Ann Intern Med.* 2021;174(5):50.
37. Banho CA, Sacchetto L, Campos GRF, Bittar C, Possebon FS, Ullmann LS, et al. Impact of SARS-CoV-2 Gamma lineage introduction and COVID-19 vaccination on the epidemiological landscape of a Brazilian city. *Commun Med (Lond).* 2022;2(1):41.
38. Bhatnagar T, Chaudhuri S, Ponnaiah M, Yadav PD, Sabarinathan RR, et al. Effectiveness of BBV152/Covaxin and AZD1222/Covishield vaccines against severe COVID-19 and B.1.617.2/Delta variant in India, 2021: a multi-centric hospital-based case-control study. *Int J Infect Dis.* 2021;2022(122):693–702.
39. Chirico F, da Teixeira Silva JA, Tsigaris P, Sharun K. Safety and effectiveness of COVID-19 vaccines: a narrative review. *Indian J Med Res.* 2022;155(1):91–104.
40. Pregelj L, Hine DC, Oyola-Lozada MG, Munro TP. Working hard or hardly working? Regulatory bottlenecks in developing a COVID-19 Vaccine. *Trends Biotechnol.* 2020;38(9):943–7.
41. Hotez PJ, Batista C, Amor YB, Ergonul O, Figueroa JP, Gilbert S, et al. Global public health security and justice for vaccines and therapeutics in the COVID-19 pandemic. *EClinicalMedicine.* 2021;39:101053.
42. Yap JFC. Response: political polarization and its impact on COVID-19 vaccine acceptance. *J Public Health.* 2023;45(3):e599.
43. Albrecht D. Vaccination, politics and COVID-19 impacts. *BMC Public Health.* 2022;22(1):96.
44. Bahi R. The geopolitics of COVID-19: US-China rivalry and the imminent Kindleberger trap. *Rev Econ Polit Sci.* 2021;6(1):76–94.
45. Italian Institute for International Political Studies. China, Russia and COVID-19: vaccine diplomacy at different capacity. <https://www.ispionline.it/en/publication/china-russia-and-covid-19-vaccine-diplomacy-different-capacity-31070> (2021).
46. Henao-Restrepo AM, Preziosi MP, Wood D, Moorthy V, Kieny MP, WHO Ebola Research, Development Team. On a path to accelerate access to Ebola vaccines: the WHO's research and development efforts during the 2014–2016 Ebola epidemic in West Africa. *Curr Opin Virol.* 2016;17:138–44.
47. Ahonkhai V, Martins SF, Portet A, Lumpkin M, Hartman D. Speeding access to vaccines and medicines in low- and middle-income countries: a case for change and a framework for optimized product market authorization. *PLoS One.* 2016;11(11):e0166515.
48. Alghamdi NS, Alghamdi SM. The role of digital technology in curbing COVID-19. *Int J Environ Res Public Health.* 2022;19(14):8287.
49. Mondal S, Mitra P. The role of emerging technologies to fight against COVID-19 pandemic: an exploratory review. *Trans Indian Natl Acad Eng.* 2022;7(1):157–74.
50. De Gagne JC, Koppel PD, Wang EJ, Rushton S, Ledbetter L, Yamane SS, et al. A systematic review of videoconferencing in health professions education: the digital divide revisited in the COVID-19 era. *Int J Nurs Educ Scholarsh.* 2023;20(1):20220068.

51. Sun X, Wandelt S, Zhang A. Vaccination passports: challenges for a future of air transportation. *Transp Policy (Oxf)*. 2021;110:394–401.
52. Estacio EV, Whittle R, Protheroe J. The digital divide: examining socio-demographic factors associated with health literacy, access and use of internet to seek health information. *J Health Psychol*. 2019;24(12):1668–75.
53. Williamson LD, Tarfa A. Examining the relationships between trust in providers and information, mistrust, and COVID-19 vaccine concerns, necessity, and intentions. *BMC Public Health*. 2022;22(1):2033.
54. Wilson K, Flood CM. Implementing digital passports for SARS-CoV-2 immunization in Canada. *CMAJ*. 2021;193(14):E486–8.
55. Mbunge E. Integrating emerging technologies into COVID-19 contact tracing: opportunities, challenges and pitfalls. *Diabetes Metab Syndr*. 2020;14(6):1631–6.
56. Li C, Liu J, Qian G, Wang Z, Han J. Double chain system for online and offline medical data sharing via private and consortium blockchain: a system design study. *Front Public Health*. 2022;10:1012202.
57. Rashid MM, Choi P, Lee SH, Kwon KR. Block-HPCT: blockchain enabled digital health passports and contact tracing of infectious diseases like COVID-19. *Sensors (Basel)*. 2022;22(11):4256.
58. WHO. Global strategy on digital health. <https://www.who.int/docs/default-source/documents/gd4dhdad2a9f352b0445bafbc79ca799dce4d.pdf> (2020).
59. Campanozzi LL, Gibelli F, Bailo P, Nittari G, Sirignano A, Ricci G. The role of digital literacy in achieving health equity in the third millennium society: a literature review. *Front Public Health*. 2023;11:1109323.
60. Fernandes A, Chaudhari S, Jamil N, Gopalakrishnan G. COVID-19 vaccine. *Endocr Pract*. 2021;27(2):170–2.
61. Soheili M, Khateri S, Moradpour F, Mohammadzadeh P, Zareie M, Mortazavi SM, et al. The efficacy and effectiveness of COVID-19 vaccines around the world: a mini-review and meta-analysis. *Ann Clin Microbiol Antimicrob*. 2023;22(1):42.
62. Hussein AARM, Hashem MK, Azizeldine MG, Shaddad AM. Prevalence and characteristics of COVID-19 vaccine breakthrough infection in Upper Egypt. *Egypt J Bronchol*. 2023;17(1):21.
63. Pooley N, Karim Abdul SS, Combadière B. Durability of vaccine-induced and natural immunity against COVID-19: a narrative review. *Infect Dis Ther*. 2023;12(2):367–87.

الاطر القانونية والتنظيمية لمشاركة البيانات الصحية الدولية: مراجعة شاملة لإدارة البيانات الصحية عبر الحدود أثناء الجائحات

الملخص

الخلفية: في العقود الأخيرة، واجهت الصحة العالمية تحديات متزايدة نتيجة الجائحات، مما أبرز الحاجة إلى آليات فعالة لمشاركة البيانات الصحية عبر الحدود. تُعد جائحة كوفيد-19 مثالاً على كيفية تسهيل الترابط العالمي لانتشار الأمراض المعدية بسرعة، مما يستدعي وضع أطر قانونية وتنظيمية قوية لإدارة البيانات الصحية على المستوى الدولي. تستعرض هذه المراجعة الأدبيات الحالية المتعلقة بالتحديات القانونية والتنظيمية المرتبطة بمشاركة البيانات الصحية الدولية.

الطرق: تم إجراء تقييم شامل للدراسات المنشورة، والتقارير الحكومية، والإرشادات من مصادر موثوقة، بما في ذلك PubMed وScopus ووثائق منظمة الصحة العالمية، مع التركيز على السنوات الأربع الماضية. يكشف التحليل عن تباينات كبيرة في الوصول إلى اللقاحات، وعمليات الموافقة عليها، والبنية التحتية التكنولوجية بين الدول، مما يعقد تنفيذ جوازات السفر الصحية الرقمية (DHPS) على المستوى العالمي.

النتائج: تشير النتائج الرئيسية إلى أن التوزيع غير العادل للقاحات، وتفاوت المعايير التنظيمية، والفجوات الرقمية تعيق فعالية جوازات السفر الصحية الرقمية في إدارة الجائحات. كما تسلط المراجعة الضوء على ضرورة التعاون الدولي لوضع معايير تنظيمية موحدة وممارسات تحمي خصوصية الأفراد وتسهل مشاركة البيانات.

الخلاصة: في الختام، يُعد معالجة الحواجز الجغرافية والتشغيلية أمام مشاركة البيانات الصحية الفعالة أمراً ضرورياً لتعزيز استراتيجيات الاستجابة العالمية للجائحات. تؤكد النتائج على أهمية تطوير أطر مرنة وقابلة للتكيف يمكنها الاستجابة بفعالية للأزمات الصحية المستقبلية. كما أن التعاون بين الحكومات والمنظمات الدولية ومقدمي التكنولوجيا أمر أساسي للتغلب على التحديات الحالية وضمان الوصول العادل إلى البيانات الصحية عبر الحدود.

الكلمات المفتاحية: مشاركة البيانات الصحية عبر الحدود، إدارة الجائحات، جوازات السفر الصحية الرقمية، الأطر التنظيمية، عدالة توزيع اللقاحات.