HHR
Health and Human Rights Journal

The Role of Civil Society in Mobilizing Human Rights Struggles for Essential Medicines: A Critique from HIV/AIDS to COVID-19

SHARIFAH SEKALALA AND BELINDA RAWSON

Abstract

In this paper, we explore the strategies utilized by civil society organizations to improve access to medicines during the HIV/AIDS and COVID-19 health crises. In particular, we seek to illuminate why some of the successful approaches for increasing access to antiretrovirals for HIV/AIDS in the early 2000s failed in creating equitable global access to COVID-19 vaccines. While civil society has historically mobilized human rights to facilitate greater access to essential medicines, we argue that earlier strategies were not always sustainable and that civil society is now mobilizing human rights in radically different ways than previously. Instead of focusing chiefly on securing an intellectual property waiver to the TRIPS Agreement, civil society organizations are now challenging vaccine injustice, rejecting the "charity discourse" that fuels Global South dependency on Global North actors in favor of scaling up manufacture in low- and middle-income countries, and moving to embed the right to access medicines in a new World Health Organization pandemic treaty with civil society organization participation and meaningful representation from low- and middle-income countries. Such approaches, we contend, will lead to more sustainable solutions in order to avert further health care disasters, like those seen with two distinct but related struggles—the fights for equitable access to essential medicines for HIV/AIDS and for COVID-19.

Sharifah Sekalala, PhD, LLB, LLM, is Professor of Global Health Law in the School of Law at the University of Warwick, Coventry, United Kingdom.

Belinda Rawson, BA, LLB, is an associate tutor and academic researcher in the School of Law at the University of Warwick, Coventry, United Kingdom.

Please address correspondence to Sharifah Sekalala. Email: sharifah.sekalala@warwick.ac.uk.

Competing interests: None declared.

Introduction

Civil society has a long history of engaged advocacy on improving access to essential medicines globally. In particular, the HIV/AIDs crisis saw civil society organizations (CSOs) at the forefront of the successful fight for wider access to antiretroviral drugs (ARVs) for HIV/AIDS treatment. In this paper, we explore the ways in which CSOs have been instrumental in facilitating access to essential medicines and how their strategies have evolved over time. Moreover, we specifically seek to understand why the earlier and more successful civil society strategies for ARVs failed as strategies for creating equitable access to COVID-19 vaccines. While previous strategies included employing powerful human rights narratives that often fed directly into successful litigation around the right to health and the right to life, they also focused on using and creating exceptions contained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to create restrictions for patenting medicines required for public health purposes. However, despite the efforts of committed civil society activists, we argue that they failed to make systemic changes in international law, and as a result, global vaccine inequities were prevalent at the height of the COVID-19 crisis. In response to this, CSOs have had to reconfigure a new movement that again employs narratives of human rights struggles, but this time advocates for the greater entrenchment of human rights in international law while simultaneously continuing to advocate for more sustained changes in intellectual property (IP) law. Thus, CSOs are pushing for a shift that relies less on expectations under IP law and charitable programs that are disease specific and focuses more on enabling poorer countries to manufacture their own COVID-19 vaccines as a mechanism of greater sovereignty and sustainability for creating access to essential medicines for future global health crises.

Method

In this paper, we use narrative as the method to explore the ways in which CSOs have used human rights to facilitate access to essential medicines for underserved Global South populations and assess whether we can observe any limitations to the approaches they have adopted. Using narrative in the study of human rights assists in the analysis of the social and political context as a background to wider questions of justice. We searched the literature in two academic databases—HeinOnline and PubMed—and focused on the strategies that CSOs employed in facilitating access to medicines across two distinct but related struggles for access to medicines: the fight for ARVs in the earlier HIV/AIDS pandemic, and more recent struggles for equitable access to COVID-19 vaccines. From the literature we searched, we found that four key narratives emerged.

The first narrative focuses on the tensions related to international IP rights embedded in the TRIPS Agreement and the way in which CSOs used international law instrumentally in the Global South. The second narrative centers on the ways in which CSOs have framed the failure of existing charity discourses in global health using the language of apartheid. The third narrative focuses on the role of manufacturing for new vaccine technologies in low- and middle-income countries (LMICs) as a mechanism to create greater access to essential medicines for Global South countries. The final narrative relates to the human rights claims that CSOs are making in a new proposed pandemic treaty in order to embed the right to access medicines in international law and create more binding obligations on states and the pharmaceutical industry.

We use the terms "Global North" and "Global South" in this paper because the struggles for essential medicines have played out along broader geographic boundaries in which the Global North has access to essential medicines at the expense of the Global South. However, we recognize that the terms Global North and Global South are problematic, and we are attentive to the fact that there are difficulties of grouping together many categories into one category. When we refer to the Global South, we mean the decolonized nations situated south of the old colonial centers of power and which comprise nations across Asia, Africa, and

Latin America.[1] Our exploration will center on the ways in which CSOs have historically mobilized human rights to facilitate greater access to ARVs for HIV/AIDS, particularly for people in the Global South, within two major pandemics—HIV/AIDS and COVID-19. This analysis of CSO engagement tells a nuanced story around the strengths and limitations of their involvement in the campaign for access to medicines. This is particularly important as we reflect on the broader ways in which CSOs can contribute to greater global health justice in the wake of the COVID-19 pandemic.

What do we mean by civil society?

The United Nations refers to CSOs as nonprofit, voluntary citizens' groups that are organized around specific issues on a local, national, or international level, and which perform a variety of services and humanitarian functions, bringing citizens' attention to governments, monitoring policies, encouraging community participation, and providing analysis and expertise.[2] For the purposes of this paper, we refer to CSOs as those voluntary organizations working in the fields of development, health, human rights, law, and medicine who utilize multifarious methods of engagement, including conducting grassroots advocacy, creating transnational alliances, challenging geopolitical norms through policy advocacy, and instigating legal challenges to bring about changes in regulation to facilitate greater access to essential medicines.

We acknowledge that civil society is not homogeneous and operates on different scales with different purposes, even in the context of single issues such as access to ARVs for people living with HIV. In this paper, when we talk about civil society, we are referring specifically to organizations and networks that focus on access to essential medicines as a unitary issue and the ways in which they organize at the transnational level, including by creating numerous coalitions.[3] Some organizations have a focus on essential medicines as part of a broader mission around humanitarian health and are located in multiple jurisdictions (e.g., Médecins Sans Frontières), while others, such as the Treatment Action Campaign, operate in one country (South Africa) and focus almost exclusively on issues around access to essential medicines (or at least did so in the earlier days). These different types and scales of civil society enable organizations to form networks and seek to influence policy at multiple governance levels, and represent the interests of global citizens through their campaigns for human rights, which challenge dominant attitudes and approaches and reshape global politics and society.[4] This has historically been evident in global fights for access to medicines, such as earlier accounts of CSOs using human rights-based approaches in campaigns for ARVs, and well as in more contemporaneous campaigns against COVID-19 vaccine injustice.[5] Civil society involvement also facilitates state accountability for human rights violations, including with regard to the right to health, and CSOs are instrumental in introducing new international norms such as greater access to medicines as part of the fundamental rights to health and life, as we discuss below.[6]

Civil society's mobilization of human rights to increase access to antiretrovirals

Human rights provide a normative framework that creates the space for CSOs to mobilize, reinforcing community agency and a means by which "the purported constraints imposed by globalization" can be contested.[7] From the 1980s onward, networks of people living with HIV and CSOs began to form advocacy groups to campaign on an array of human rights issues, including addressing AIDS-related stigma and discrimination as well as improving access to medicines. Civil society groups were at the forefront of designing innovative and effective initiatives to address HIV/AIDS and increase access to ARVs, particularly for those populations of the developing world who have been consistently disproportionately impacted by public health threats due to prevailing global inequality (such as in Sub-Saharan Africa).[8] The success of countries such as Uganda and Thailand in controlling the HIV/AIDS epidemic has also been attributed to a high level of civil society engagement.[9] We will now

consider some of the earlier strategies employed by CSOs in promoting human rights to increase access to medicines.

CSOs played a pivotal role in early litigation efforts at the national level (particularly in Central and Latin America, India, and Sub-Saharan Africa) in order to ensure that courts enshrined the right to access medicines as part of the right to health.[10] In order to do so, CSOs acting mainly as *amicus curiae* highlighted the interrelated nature of the right to life and the right to health and argued that in instances involving life-threatening diseases such as AIDS, access to essential medicines is necessary to realize both rights.[11] This strategic litigation by CSOs was often successful and changed health outcomes for millions of people living with HIV in the Global South. For instance, in 2002, the Treatment Action Campaign and others relied on the right to health, as enshrined in the Constitution of South Africa, to legally compel the South African government to provide the ARV nevirapine free to all pregnant women living with HIV who could not afford the drug, in order to minimize parent-to-child transmission.[12] Additionally, civil society actions in India and Thailand led to GSK announcing the withdrawal of its patent application for some formulations of ARVs.[13]

Of particular concern to CSOs and scholars was that the World Trade Organization's (WTO) TRIPS Agreement was posing a significant barrier to timely and affordable access to ARVs for the treatment of HIV/AIDS.[14] Throughout the 1980s and 1990s, an international IP regime was crafted by states and major pharmaceutical corporations, culminating in the TRIPS Agreement upon the establishment of the WTO in 1995. Prior to this, medicines were considered by many governments to be too vital to be subject to patentability, and yet the TRIPS Agreement requires the implementation of minimum standards of IP protection by WTO member states, including patents for pharmaceutical products, for a minimum period of 20 years.[15] During this time, patent owners can restrict the ability of others to use the patent, thereby keeping the price of the patented product high. This came to a head with the development of ARVs, with the initial average cost of a triple combination of ARVs being US$10,000–$15,000 per patient per year in the late 1990s. While the incredibly high cost of ARVs led to disproportionate mortality rates globally, it was populations in Global South countries that bore the brunt of these excessive prices due to patent restrictions.[16]

CSOs (particularly in Thailand, Brazil, South Africa, India, Kenya, and Uganda) formed alliances and joined forces with health care providers and international organizations to break this deadlock.[17] The momentum for the creation of the WTO Doha Declaration on the TRIPS Agreement and Public Health in 2001, which reaffirms WTO member states' rights to make full use of flexibilities within the TRIPS Agreement in order to protect public health and maximize access to medicines, can be ascribed to civil society engagement.[18] It was envisaged at the time that the Doha Declaration would assist in the resolution of the accessibility issues and make ARVs more affordable and widely accessible globally. These earlier efforts in creating access to ARVs were highly successful through not only achieving price reductions for ARVs and by helping facilitate a market in generic medicines (which led to pharmaceutical corporations reducing their prices) but also through the establishment of health programs that created free access to drugs for other diseases, such as malaria and tuberculosis. This underscored human rights values such as accountability and representation of marginalized populations through the work undertaken on key populations.[19] However, despite these efforts, continued trade-related pressure against generics manufacture by large pharmaceutical corporations threatened the sustainability of the successful expansion in ARV access in LMICs.[20]

For Upendra Baxi, the contemporary human rights movement predominantly arose "to give voice to human suffering, to make it visible, and to ameliorate it."[21] Baxi describes "meta-narratives" as being the "global stories about power and struggles against power," which are invoked by the universalism of human rights.[22] In the struggle for ARVs, CSOs used human rights narratives and morality frames to communicate their positions and seek to

change the consensus.[23] For instance, the struggle for access to ARVs was framed by CSOs as a broader story of injustice in which a significant number of impoverished children were being orphaned and children with HIV who lived in the Global South were doomed to die before their fifth birthday, while the majority of mainly white middle-class adults who were HIV positive in the Global North could live long, comfortable, and fulfilling lives.[24] Despite these successes, Jan Aart Scholte notes that due to different resources, priorities, and outlooks, civil society networks often struggle to sustain collective strategies into the future.[25] This is in effect what happened with broader issues around access to ARVs in the wake of the Doha Declaration, which culminated in the failure to secure equitable access to a COVID-19 vaccine.

Conceptualizing civil society failure post-Doha

While originally seen to be a major victory for civil society and poorer nations and a development that "captured the middle ground" between the positions adopted by countries in the Global South and Global North, the Doha Declaration has been obstructed by the use of "TRIPS-plus" provisions in free trade agreements, trade retaliation, and political pressures, as well as by the stricter scrutiny that Global South countries are faced with compared to Global North countries.[26] These TRIPS-plus rules that can extend patent terms beyond 20 years and limit the granting of compulsory licenses help create and sustain strong pharmaceutical monopolies that result in delayed availability and increased costs to governments and individuals of essential medicines.[27]

The resourcing of CSOs constrains the ways in which they can sustain energy for activist struggles, especially if their agendas are not aligned with those of their funders. For instance, many CSOs involved in international development mirror the priorities of their home states due to the reliance on funding streams.[28] In the field of HIV/AIDS, as funding became institutionalized, many CSOs shifted their focus toward service delivery, which greatly restricted their scope and capacity to continue activist struggles.[29] Donors with a more technical (and sometimes technocratic) approach, such as the Bill & Melinda Gates Foundation, have increasingly come to dominate the field. A growing shift away from policy monitoring and critical dialogue and toward more technical implementation and support appears to be a key tendency at the beginning of the fourth decade of the HIV/AIDS epidemic.[30] This reliance on donor funding has meant that many CSOs that had been instrumental in pushing human rights values as part of an access to medicines movement for ARVs transitioned into service delivery or more technocratic aspects of ensuring access to medicines, such as drug quality.

Conversely, the establishment of free drug programs through aid packages such as those run through the Global Fund to Fight AIDS, Tuberculosis and Malaria also created a situation in which global access to essential medicines was seen as a charitable exception to patent rules.[31] While the implementation of human rights has been a pillar of the Global Fund's strategic plan for the last decade, this model of charitable giving in which ARVs are provided free of charge made it more difficult for broader arguments around patents to be sustained by CSOs.[32]

Additionally, some CSOs became co-opted by pharmaceutical corporations that changed tack in the wake of the Doha Declaration. Many of these corporations invested huge resources into refocusing the importance of international IP rights. This was done through the promotion of a discourse around counterfeiting, which spuriously undermined generic drugs by casting aspertions about the threat of "fake drugs." Some CSOs ended up expending their energy on rooting out this threat, which presented a distraction from the broader fight for further concrete changes in the international IP system.[33] Moreover, the pharmaceutical lobby pushed hard for specific initiatives such as the Anti-Counterfeiting Trade Agreement, which spurred local counterfeiting laws in many Global South countries, as well as workshops for CSOs and policy makers that served to again divert attention from international IP rights to falsified or "fake

drugs." Such "fake drugs" were highly criminalized and described in incendiary terms such as "medical terrorism."[34] These developments created a chilling effect on CSOs that were pushing for access to essential medicines, as it confusingly distorted the lines between different categories of medicines and pushed these organizations into perpetually defending the quality of generic medicines, thereby shrinking the space for continued activism.[35]

Structurally, CSOs have always struggled to maintain broad coalitions, especially in areas where they need both health and non-health actors.[36] Having a well-developed awareness of the heterogeneity of populations and circumstantial disparities that lead to varying degrees of suffering, while simultaneously trying to build momentum for broader issues at the macro level, CSOs with more localized or regional agendas became frustrated or experienced fatigue in undertaking their advocacy work. Baxi refers to this type of exhaustion as "rights weariness."[37] For instance, CSOs from the Global North adopted radically different approaches to those in the Global South around facilitating access to essential medicines. While many organizations in the Global North focused on trying to change the TRIPS system to gain access to lifesaving treatments, many organizations in the Global South were convinced that there were broader structural issues that needed to be addressed, such as the lack of access to housing or health care, which limited the viability of many of the existing treatment options.[38] Changes to these social determinants of health such as health care and housing implicate broader social economic rights that are harder for CSOs to push for consistently.[39]

Vaccine inequity: New threats, same old struggles

The COVID-19 pandemic reignited these old struggles for access to medicines. Despite the optimism created by the development of several vaccine candidates globally, international IP laws protected pharmaceutical monopolies and led to an inequitable global distribution of COVID-19 vaccines. The bulk of vaccines were developed and manufactured in the Global North and purchased by governments in those countries to be stockpiled for their own populations, a practice sometimes described as "vaccine hoarding" or "vaccine nationalism."[40] The World Health Organization responded to these concerns through the establishment of COVAX, a donations-based mechanism led by Gavi, the Vaccine Alliance and the Coalition for Epidemic Preparedness Innovations and supported by financing from the Gates Foundation. COVAX is the vaccine pillar of the Access to COVID-19 Tools Accelerator, which relied on wealthy donors to purchase vaccines that would be pooled for LMICs. While COVAX demonstrated multilateral cooperation and solidarity in a pandemic, it also illuminated the challenges of relying on the public-private partnership model that dominates global health governance.[41]

While COVAX was originally heralded as the "solution" to ending the pandemic, this scheme has been undermined by severe shortages of vaccines caused by the hoarding of "rich and manufacturing countries."[42] As a result, the gap in inoculation rates between poor and rich countries is stark. As of early July 2022, three in four people in high-income countries had received at least one dose of the COVID-19 vaccine, compared to one in five people in low-income countries.[43] By mid-2022, most countries in the Global North had achieved the World Health Organization's target of vaccinating 70% of their populations, while many countries in the Global South sat at around 20% and struggled to increase their vaccination rates.[44]

New alliances for old problems

In response to global vaccine injustice, The People's Vaccine Alliance—a transnational civil society alliance created in 2020—campaigns to end "vaccine apartheid," declaring that COVID-19 vaccines are a global public good and that distribution must be based on need, not on ability to pay. The alliance has placed immense pressure on WTO member states to urgently agree to temporarily suspend IP rules using "flexibilities" built into the TRIPS Agreement, and on states to persuade pharmaceutical giants to share vaccine technology and technical

know-how through the World Health Organization's COVID-19 Technology Access Pool and the South African mRNA hub.[45] The COVID-19 Technology Access Pool is a platform for developers of COVID-19 therapeutics, diagnostics, vaccines, and other health products to voluntarily share their IP, knowledge, and data through the use of voluntary non-exclusive licenses and royalties in order to scale up global access to COVID-19 health technologies.[46] However, this platform ultimately failed to meet expectations, as the pharmaceutical industry refused to engage with the initiative, instead preferring to protect its short-term exorbitant profits over global public health aims.[47]

The People's Vaccine Alliance has also heavily criticized the COVAX mechanism for lacking transparency about the deals it makes with pharmaceutical corporations, for not meaningfully including civil society or Global South countries in strategic decisions, for not discouraging wealthy countries from entering into bilateral supply deals with pharmaceutical corporations, and for failing to use its purchasing power to encourage corporations to share the science, knowledge, and technology behind their vaccines to scale up global production.[48] As we have established, these lines of contestation are not new and resemble the earlier arguments made by CSOs such as Treatment Action Campaign in relation to patented medicines for HIV/AIDS and hepatitis C.[49] Yet failures to successfully challenge pro-patent regimes at the international as well as national levels have led to CSOs now using human rights in radically different ways from earlier efforts, such as by using the language of apartheid to frame access to medicines as a human right and rejecting the charity discourse that reinforces a relationship of dependency between countries in the Global North and the Global South.

Using the language of apartheid to challenge vaccine injustice

To drive its agenda, the People's Vaccine Alliance has specifically adopted the evocative terms "pharmaceutical monopolies" and "vaccine apartheid," as well as the notion of "vaccine justice," to advance the narrative that COVID-19 vaccine inequality is a destructive manifestation of enduring capitalist and imperialist agendas.[50] According to E. Tendayi Achiume, United Nations Special Rapporteur on racism, the persistent forms of structural racism and xenophobia that are driving vaccine apartheid today are the same types of racism and xenophobia that drove the South African apartheid from the 1950s to the 1990s.[51] Thus, for civil society to invoke "apartheid" is to remind us of a shared humanity, including the struggles of South Africans to overcome their country's colonially imposed racial segregation policies, as well as the continuing human rights struggles faced by a multitude of populations all over the world who are still experiencing the devastating legacies of colonization. Utilizing this language and these forms of narrative are hence a powerful way to articulate the broader issues underlying vaccine inequity as human rights violations, as well as a way to effectively emphasize the scale of the moral failure in driving COVID-19 vaccine inequity.[52]

Rejecting charity: Critiques of COVAX in favor of manufacturing

In some ways, global vaccine inequity during the COVID-19 pandemic further exemplified the limitation of earlier international IP struggles that failed to scale up the manufacturing of medicines to the extent needed to protect the populations of LMICs from being disproportionately impacted by future pandemics. While the Medicines Patent Pool was instrumental in negotiating licenses with patent holders and sublicensing to generic manufacturers and product developers in LMICs for treatments for HIV and for COVID-19, large pharmaceutical corporations based in the Global North have continuously found ways to boycott the scale-up of COVID-19 manufacturing in LMICs.[53] With the exception of India, which already had a burgeoning pharmaceutical industry due to the fact that it had taken advantage of TRIPS flexibilities in order to build its industry, many LMICs had no manufacturing capacity to produce new mRNA vaccines when the COVID-19 crisis hit. The pandemic illustrated the limitations of the entire Global South relying

on just India and a few other countries such as Thailand and Brazil for access to vaccines. This lack of manufacturing options for many countries in the Global South has led to a consolidation of power in transnational corporations and a "discounts + aid" solution, which encoded a "charity discourse" into the global access crisis, resulting in LMICs becoming dependent on high-income countries for access to essential medicines.[54] Traditional approaches based on charity "distract from actionable solutions to address the unique challenges of chronic social problems" because the underlying forces that create those conditions are not addressed.[55] The COVID-19 pandemic illustrated this starkly when countries in the Global South realized that they were still constrained by the same international patent rules under TRIPS obstructing the sharing of new technologies and technical know-how to scale up manufacture of essential medicines. Instead of dealing with the failures of the international patent system head on, wealthy countries in the Global North, together with large pharmaceutical corporations, created new narratives that decried the logistical impossibility of countries in the Global South manufacturing their own vaccines. This was despite assertions to the contrary by CSOs such as Médecins Sans Frontières, which had already identified 120 pharmaceutical manufacturers across, Africa, Asia, and Latin America with the technical capabilities to manufacture high-quality mRNA vaccines in 2021.[56]

CSOs have and continue to employ human rights advocacy in global health governance to challenge IP rights. Through direct engagement with international organizations and United Nations bodies such as UNAIDS and the World Health Organization, and through the application of pressure on organizations such as the WTO to respect rights-based obligations relating to public health, CSO engagement is part of the broader expansion of rights-based governance for global health. For instance, the Human Rights Council has recently drafted a new resolution relating to access to medicines, vaccines, and other health products in the context of the right to health. This resolution was led by Global South countries and supported by CSOs, and it explicitly recognizes the need for international cooperation among states and with international organizations, civil society, and the private sector "involved at all stages of the pharmaceuticals value chain, including research and development, manufacture, distribution and supply of pharmaceutical products" to ensure the right to health.[57]

As part of these efforts, CSOs pushed for greater access to manufacturing in the Global South in order to increase self-sufficiency and meet the needs of LMICs with dangerously under-vaccinated populations. As a result of this push and in light of the failures of COVAX, a new initiative was devised with the support of the World Health Organization and the Medicines Patent Pool to scale up manufacturing of vaccines with local producers in LMICs. The global mRNA technology transfer hub was established in South Africa at Afrigen Biologics and Vaccines in July 2021 to develop and produce mRNA vaccines at scale.[58] The hub used publicly available information on Moderna's mRNA COVID-19 vaccine to develop a comparable vaccine and is building capacity in LMICs for the manufacture of such vaccines. While Moderna agreed in October 2021 not to enforce patents on its COVID-19 vaccine, it would not agree to share the technical knowledge and expertise on how the vaccine is made.[59]

In February 2022, the World Health Organization announced that Egypt, Kenya, Nigeria, Senegal, South Africa, and Tunisia would be among the first recipients to benefit from the technology transfer scheme, and in the following month, Argentina and Brazil became the first countries to receive technology transfer training in mRNA vaccines at Afrigen.[60] While this scheme yields enormous promise and could foreshadow more sustainable solutions in scaling up the manufacture and distribution of essential medicines, and in increasing pandemic preparedness, LMICs will not benefit from the scheme as quickly as they would have had pharmaceutical corporations agreed to transfer technology to them sooner. Given that the mRNA hub's reverse-engineered vaccine is new, and recipient countries have been engaging in

mRNA training at Afrigen and receiving the vaccine technology from the mRNA hub, the vaccines will not be available to the public until they have been deemed safe and efficacious after the completion of the clinical trial period, toward the end of 2023.[61] Additionally, there is a lack of certainty as to whether patent holders such as Moderna will assert IP rights for technology transfers outside of Sub-Saharan Africa, which makes it difficult to ensure the long-term sustainability of these new hubs.

Embedding the right to access medicines in a new pandemic treaty

The failures in ensuring equitable access to COVID-19 vaccines globally are symptomatic of global inequality and a fragmented global health governance system. Many CSOs have called for the right to access essential medicines to be embedded as an international norm in a new "pandemic treaty." On May 31, 2021, the 74th World Health Assembly decided to establish a Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, and in a historic special session on November 28, 2021, the assembly established an intergovernmental negotiating body (INB) to strengthen pandemic prevention, preparedness, and response by drafting a new convention or agreement under the auspices of the World Health Organization.[62]

While the International Health Regulations, the current legally binding global framework for preparing for and responding to health emergencies, create rights and obligations for countries in the prevention of public health events, they are imprecise, especially around the extent of the duty to assist other countries.[63] Importantly, as Katrina Perehudoff et al. argue, the pandemic treaty is an opportunity to address seven "substantive areas for effective and equitable access to medical countermeasures" through creating conditions for government-funded research and development; mandating technology transfer from vaccine developers (including building manufacturing and regulatory capacity globally); requiring governments to enact legislation to facilitate the sharing of IP and knowledge; streamlining regulatory standards and processes; ensuring greater transparency on a range of issues relating to the development, financing, and procurement of medicines and medical products; and establishing inclusive governance mechanisms to ensure the meaningful representation of LMICs.[64]

The pandemic treaty is also seen as a way to resolve some of the main problems that have led to the widespread social and economic devastation caused by health crises such as HIV/AIDS and COVID-19, and to address the significant gaps in international law that recently fueled vaccine injustice and the deepening of a multitude of inequalities.[65] Civil society has been leading the charge in keeping human rights on the pandemic treaty's drafting agenda and further entrenching the right to access essential medicines as an international norm in global health law. The Civil Society Alliance for Human Rights in the Pandemic Treaty has devised the "Human Rights Principles for a Pandemic Treaty," which emphasize the need for strong participatory approaches with civil society in all decision-making processes and greater international cooperation (principle 1), enhanced human rights protection and human rights-based responses to public health emergencies (principles 2, 6, 8, and 10), and effective remedies for human rights violations (principle 7).[66] Principles 3 and 4 in particular relate to ensuring equitable access to medicines in the context of a pandemic by strengthening public health systems globally and by placing an explicit prohibition on states and third parties to not unduly hamper access.

Taken together, these principles expressly recognize the failures in states' handling of past health crises and pave a way to more equitable policy solutions during public emergencies. The principles are also aligned with the Sustainable Development Goals in relation to universal health coverage, and the United Nations High Commissioner for Human Rights' call for the treaty to be grounded in human rights.[67] Some of these principles were alluded to in the INB's June report of public hearings on the drafting of the treaty, particularly around transparency and accountability, as well as equity, which "would require upholding human rights

and guaranteeing the non-discriminatory scope, implementation and governance of the potential instrument."[68] The INB also noted that several participants raised the issue of the pandemic treaty's relationship to other international instruments relating to health, including human rights conventions, indicating that any new instrument should be consistent in order to strengthen those well-established processes.[69]

While there have now been several concerted efforts to ensure more meaningful participation by civil society into the new pandemic treaty, the approach taken by the INB has been specifically criticized by the Civil Society Alliance for Human Rights in the Pandemic Treaty as being exclusionary and for failing to facilitate effective participation by CSOs in the drafting of the treaty's provisions.[70] The alliance has vehemently resisted this participatory exclusion and continues to push for the inclusion of provisions in the pandemic treaty that explicitly apply the human rights lessons learned from past health crises (as well as those learned from COVID-19) and build in core human rights standards from the outset.[71] This demonstrates that CSOs are actively facilitating a greater integration of rights within binding legal instruments, which did not occur when the Doha Declaration was drafted.

Conclusion

The COVID-19 crisis has involved several human rights violations, though none was more prominent than the continued failure to create greater global access to COVID-19 vaccines. This paper has illustrated the ways in which civil society have been integral to previous access to medicines struggles and how successes during the earlier HIV/AIDS crisis were limited by the continued resistance of large pharmaceutical corporations against generics manufacture and price reductions. These developments resulted in COVID-19 vaccine inequity, with devastating health outcomes for people living in the Global South. CSOs are now mobilizing human rights in radically different ways than they have previously. While continuing to lobby for a TRIPS waiver that would explicitly deal with broader global health emergencies, they are also challenging vaccine injustice using the powerful language of apartheid, rejecting the "charity discourse" that sustains a relationship of dependency between Global North and Global South countries by encouraging greater manufacturing of vaccines in the Global South, as well as advocating for greater integration of human rights norms in global health law via a new pandemic treaty. We argue that these combined strategies of CSOs are integral to offering sustainable long-term solutions to issues around access to medicines to ensure that Global South populations are not disproportionately affected by the health crises of the future.

References

1. V. Prashad, *The Darker Nations: A People's History of the Third World* (New York: New Press, 2007).

2. United Nations, "Civil Society," https://www.un.org/en/civil-society/page/about-us.

3. J. A. Scholte, "Global Civil Society: Changing the World?," University of Warwick Working Paper No. 31/99 (Coventry: Centre for the Study of Globalisation and Regionalisation, 1999).

4. R. Lencucha, R. Labonte, and M. Rouse, "Beyond Idealism and Realism: Canadian NGO/Government Relations during the Negotiation of the FCTC," *Journal of Public Health Policy* 31/1 (2010); H. Yanacopulos and M. Ballie Smith, "The Ambivalent Cosmopolitanism of International NGOs," in A. J. Bebbington, S. Hickey, and D. C. Mitlin (eds), *Can NGOs Make a Difference? The Challenge of Development Alternatives* (London: Zed Books, 2008).

5. W. Hein, S. Bartsch, and L. Kohlmorgen (eds), *Global Health Governance and the Fight against HIV/AIDS* (New York: Palgrave Macmillan, 2007); N. Ford, A. Calmy, and E. J. Mills, "The First Decade of Antiretroviral Therapy in Africa," *Globalization and Health* 7/1 (2011); R. Parker, "Grassroots Activism, Civil Society Mobilization, and the Politics of the Global HIV/ AIDS Epidemic," *Brown Journal of World Affairs* 21/2 (2011).

6. T. G. Weiss, T. Carayannis, and R. Jolly, "The 'Third' United Nations," *Global Governance* 15/1 (2009).

7. L. London and H. Schneider, "Globalisation and Health Inequalities: Can a Human Rights Paradigm Create Space for Civil Society Action?," *Social Science and Medicine* 74/1 (2012).

8. B. Rau, "The Politics of Civil Society in Confronting HIV / AIDS," *International Affairs* 82/2 (2006).

9. Ibid.; J. C. Mubangizi, and B. K. Twinomugisha, "The Right to Health Care in the Specific Context of Access to

HIV/ AIDS Medicines: What Can South Africa and Uganda Learn from Each Other?," *African Human Rights Law Journal* 10/1 (2010).

10. H. V. Hogerzeil, M. Samson, J. V. Casanovas, et al., "Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?," *Lancet* 368 (2006); E. K. Oke, "The Right to Health in Pharmaceutical Patent Dispute," South Centre Research Paper 145 (February 9, 2022).

11. S. Sekalala, *Soft Law and Global Health Problems: Lessons from Responses to HIV/AIDS, Malaria and Tuberculosis* (Cambridge: Cambridge University Press, 2017), pp. 95–117; A. E. Yamin, "Promoting Health Equity in Health: What Role for the Courts?," *Health and Human Rights Journal* 2/16 (2014).

12. E. Baimu, "The Government's Obligation to Provide Anti-retrovirals to HIV-Positive Women in an African Human Rights Context: The South African *Nevirapine* Case," *African Human Rights Law Journal* 2 (2002).

13. E. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (Diemen: AMB, 2009).

14. Ibid.; B. Waning, E. Diedrichsen, and S. Moon, "A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries," *Journal of the International AIDS Society* 13/35 (2010); R. Horner, "The Global Relevance of India's Pharmaceutical Patent Laws," *Economic and Political Weekly* 48/31 (2013).

15. N. Ford, E. 't Hoen, and T. van Schoen-Angerer, "Editorial: Discussions in Geneva, Demonstrations in Delhi: Why Incentives for Drug Innovation Need Reviewing," *Drug Discovery Today* 12/9–10 (2007).

16. Médecins Sans Frontières, "Patents, Prices and Patients: The Example of HIV/AIDS" (May 1, 2002), https://www.msf.org/patents-prices-patients-example-hivaids; E. Wood, J. S. G. Montaner, D. R. Bangsberg, et al., "Expanding Access to HIV Antiretroviral Therapy among Marginalized Populations in the Developed World," *AIDS* 17/17 (2003).

17. N. Ford, A. Calmy, and E. J. Mills, "The First Decade of Antiretroviral Therapy in Africa," *Globalization and Health* 7/33 (2011).

18. Declaration on the TRIPS Agreement and Public Health, TRIPS WT/MIN(01)/DEC/2 (2001).

19. Sekalala (see note 11).

20. T. Owen, "The 'Access to Medicines' Campaign vs. Big Pharma: Counter-Hegemonic Discourse Change and the Political Economy of HIV/AIDS Medicines," *Critical Discourse Studies* 11/3 (2014).

21. U. Baxi, "Voices of Suffering, Fragmented Universality, and the Future of Human Rights," in B. H. Weston and S. P. Marks (eds), *The Future of International Human Rights* (New York: Transnational Publishers, 1999).

22. Ibid.

23. Lencucha et al. (see note 4).

24. UNAIDS, *Report on the Global HIV/AIDS Epidemic* (Geneva: UNAIDS, 2002), p. 46.

25. J. A. Scholte, "Civil Society and Democratically Accountable Global Governance," *Government and Opposition* 39/2 (2004).

26. J. T. Gathii, "The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties," *Harvard Journal of Law and Technology* 15/2 (2002); 't Hoen, 2009 (see note 13); G. Krikorian and E. Torreele, "Perspective: We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis," *Health and Human Rights Journal* 23/1 (2021), pp. 119–127.

27. B. Tenni, H. V. J Moir, B. Townsend, et al. (2022) "What Is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review," *Globalization and Health* 18/40 (2022).

28. A. J. Bebbington, S. Hickey and D. C. Mitlin, "Introduction," in A. J. Bebbington, S. Hickey, and D. C. Mitlin (eds), *Can NGOs Make a Difference? The Challenge of Development Alternatives* (London: Zed Books, 2008).

29. S. R. Sekalala, "Who Gets to Sit at the Table? Interrogating the Failure of Participatory Approaches within a Right to Health Framework," *International Journal of Human Rights* 21/7 (2016); J. Smith, *Civil Society Organizations and the Global Response to HIV/AIDs* (London: Routledge, 2017).

30. Parker (see note 5).

31. Owen (see note 20).

32. S. Sekalala and T. Haastrup, "What Have Rights Got To Do With It? Evaluating 'Human Rights' as a Practice within the Global Fund," *Global Health Governance* (March 15, 2018), https://blogs.shu.edu/ghg/2018/03/15/what-have-rights-got-to-do-with-it-evaluating-human-rights-as-a-practice-within-the-global-fund/.

33. J. Cohn, T. von Schoen-Angerer, E. Jambert, et al., "When Falsified Medicines Enter the Supply Chain: Description of an Incident in Kenya and Lessons Learned for Rapid Response," *Journal of Public Health Policy* 34/1 (2013); E. Cloatre, "Fluid Legal Labels and the Circulation of Socio-technical Objects: The Multiple Lives of 'Fake' Medicines'," in D. Cowan and Wincott (eds), *Exploring the "Legal" in Socio-legal Studies* (London: Palgrave Macmillan, 2016).

34. M. Quet, "Values in Motion: Anti-counterfeiting Measures and the Securitization of Pharmaceutical Flows," *Journal of Cultural Economy* 10/2 (2017).

35. Ibid.; A. Rens, "Collateral Damage: The Impact of ACTA and the Enforcement Agenda on the World's Poorest People," *American University International Law Review* 26/3 (2011); J. Liberman, "Combating Counterfeit Medicines and Illicit Trade in Tobacco Products: Minefields in Global Health Governance," *Journal of Law and Medical Ethics* 40/2 (2012).

36. J. Shiffman, "Four Challenges That Global Health Networks Face," *International Journal of Health Policy Management* 6/4 (2017).

37. Baxi (see note 21).

38. Parker (see note 5).

39. K. Roth, "Defending Economic, Social and Cultural Rights: Practical Issues Faced by an International Human Rights Organization," *Human Rights Quarterly* 26/1 (2004).

40. United Nations, "Vaccine Nationalism, Hoarding Putting Us All at Risk, Secretary-General Tells World Health Summit, Warning COVID-19 Will Not Be Last Global Pandemic" (October 24, 2021), https://www.un.org/press/en/2021/sgsm20986.doc.htm.

41. K. T. Storeng, A. de Bendy Puyvallée, and F. Stein, "COVAX and the Rise of the 'Super Public Private Partnership' for Global Health," *Global Public Health* (2021).

42. Gavi, "COVAX Explained" (September 3, 2020), https://www.gavi.org/vaccineswork/covax-explained; World Health Organization, "WHO Director-General's Opening Remarks at the Media Briefing – 29 June 2022" (June 29, 2022), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing---29-june-2022.

43. Data Futures Platform, "Global Dashboard for Vaccine Equity," https://data.undp.org/vaccine-equity/.

44. "UN Analysis Shows Link between Lack of Vaccine Equity and Widening Poverty Gap," *UN News* (March 28, 2022), https://news.un.org/en/story/2022/03/1114762.

45. People's Vaccine Alliance, "FAQ," https://peoplesvaccine.org/faq/.

46. World Health Organization, "WHO COVID-19 Technology Access Pool" (2020), https://www.who.int/initiatives/covid-19-technology-access-pool.

47. E. 't Hoen, C. Garrison, P. Boulet, et al., "Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations," background paper 6 commissioned by the Independent Panel for Pandemic Preparedness and Response (2021), https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccinationlegal-aspects.pdf.

48. Ibid.

49. Treatment Action Campaign, "The Treatment Action Campaign (TAC) Calls on Government to Amend South Africa's Patents Act and Protect Our Right to Health" (November 16, 2011), https://www.tac.org.za/news/the-treatment-action-campaign-tac-calls-on-government-to-amend-south-africas-patents-act-and-protect-our-right-to-health/; Treatment Action Campaign, "Should the Medicines Patent Pool Work on Hepatitis C Medicines?" (May 5, 2015), https://www.tac.org.za/news/should-the-medicines-patent-pool-work-on-hepatitis-c-medicines/.

50. A. Marriott and A. Maitland, *Policy Brief: The Great Vaccine Robbery* (People's Vaccine Alliance, 2021), https://www.oxfamitalia.org/wp-content/uploads/2021/07/The-Great-Vaccine-Robbery-Policy-Brief-final.pdf.

51. E. T. Achiume, "Racism Leads to 'Vaccine Apartheid' – UN Human Rights Expert," *UN News* (December 8, 2021), https://media.un.org/en/asset/k1b/k1b6guwxou.

52. S. S. Bajaj, L. Maki, and F. C. Stanford, "Vaccine Apartheid: Global Cooperation and Equity," *Lancet* 399/10334 (2022).

53. Medicines Patent Pool, "35 Generic Manufacturers Sign Agreements with MPP to Produce Low-Cost, Generic Versions of Pfizer's Oral COVID-19 Treatment Nirmatrelvir in Combination with Ritonavir for Supply in 95 Low- and Middle-Income Countries" (March 17, 2022), https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and.

54. Ibid.

55. Bajaj et al. (see note 52).

56. Médecins Sans Frontières, *Technical Brief: Pharmaceutical Firms across Asia, Africa and Latin America with Potential to Manufacture mRNA vaccines, Technical Brief* (December 16, 2021), https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines.

57. Human Rights Council, Draft Resolution 50: Access to Medicines, Vaccines and Other Health Products in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, UN Doc. A/HRC/50/L.13/Rev.1 (2022).

58. World Health Organization, "The mRNA Vaccine Technology Transfer Hub," https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub.

59. E. Greenberg and K. K. Phillips, "The Quest to Boost Africa's Fight Against COVID-19," Open Society Foundations (October 12, 2022), www.opensocietyfoundations.org/voices/the-quest-to-boost-africa-s-fight-against-covid-19.

60. World Health Organization, "WHO Announces First Technology Recipients of mRNA Vaccine Hub with Strong Support from African and European Partners" (February 18, 2022), https://www.un.org/africarenewal/magazine/who-announces-first-technology-recipients-mrna-vaccine-hub-strong-support-african-and; Pan American Health Organization, "Latin American Manufacturers Complete First Training in mRNA Technology in Bid to Improve Regional Vaccine Production" (March 24, 2022), https://www.paho.org/en/news/24-3-2022-latin-american-manufacturers-complete-first-training-mrna-technology-bid-improve.

61. World Health Organization, "WHO Press Conference on COVID-19, Monkeypox and Other Global Health Issues – 5 October 2022" (October 6, 2022), www.who.int/publications/m/item/monkeypox--covid-19---other-global-health-issues-virtual-press-conference---5-October-2022.

62. World Health Assembly, Resolution WHA 74.7:

Strengthening WHO Preparedness for and Response to Health Emergencies (May 31, 2021); World Health Assembly, Second Special Session Provisional Agenda Item 2: The World Together; Establishment of an Intergovernmental Negotiating Body to Strengthen Pandemic Prevention, Preparedness and Response, SSA2/CONF./1Rev (November 28, 2021), https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2_CONF1Rev1-en.pdf.

63. R. Habibi, S. J. Hoffman, G. L. Burci, et al., "The Stellenbosch Consensus on Legal National Responses to Public Health Risks: Clarifying Article 43 of the International Health Regulations", *International Organizations Law Review* 19 (2022).

64. K. Perehudoff, E. 't Hoen, K. Mara, et al., "A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-How and Technology," *BMJ Global Health* 7 (2022).

65. T. F. Hodgson, M. S. Carmona, and M. Podmore, "States Cannot Negotiate a Pandemic Treaty Alone," *BMJ* 377 (2022).

66. Civil Society Alliance for Human Rights in the Pandemic Treaty, "Draft Human Rights Principles for a Pandemic Treaty," https://www.icj.org/wp-content/uploads/2022/04/11-April-2022-Human-Rights-Principles-for-a-Pandemic-Treaty-.pdf.

67. Global Health Centre, *Policy Brief: Why and How to Reflect Universal Health Coverage in the Pandemic Treaty* (Geneva: Graduate Institute of International and Development Studies, 2022); Office of the United Nations High Commissioner for Human Rights, "Negotiations for International Instrument on Pandemic Preparedness Must Be Guided by Human Rights: UN experts" (May 20, 2022), https://www.ohchr.org/en/statements/2022/05/negotiations-international-instrument-pandemic-preparedness-must-be-guided-human.

68. World Health Organization, *First Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response: Outcomes of the First Round of Public Hearings* (June 1, 2022), https://apps.who.int/gb/inb/pdf_files/inb1/A_INB1_10-en.pdf.

69. Ibid.

70. Global Initiative for Economic, Social and Cultural Rights, "The 'Civil Society Alliance for Human Rights in the Pandemic Treaty' on the Importance of Participation to Advance #Human Rights and the Right to Health" (April 12, 2022), https://www.gi-escr.org/latest-news/the-civil-society-alliance-for-human-rights-in-the-pandemic-treaty-on-the-importance-of-participation-to-advance-human-rights-and-the-right-to-health; International Commission of Jurists, "Civil Society Alliance for Human Rights in the Pandemic Treaty Warns World Health Organization of Risk of Inadequate Consultation" (April 12, 2022), https://www.icj.org/civil-society-alliance-for-human-rights-in-the-pandemic-treaty-warns-world-health-organization-of-risk-of-inadequate-consultation/.

71. International Commission of Jurists, "Global Organizations' Statement Repeats Calls on the World Health Organization to Ensure a Pandemic Treaty Grounded in Human Rights Law and Standards" (March 12, 2022) https://www.icj.org/global-organizations-statement-repeat-calls-on-the-world-health-organization-to-ensure-a-pandemic-treaty-grounded-in-human-rights-law-and-standards/.