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International rules on health data sharing for a new pandemic agreement

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International Rules on Health Data Sharing for a New Pandemic Agreement

Anna Holzscheiter & Maria Weickardt Soares

Summary

The negotiations on the Pandemic Agreement offered a key opportunity for the World Health Organization's (WHO) 194 Member States to address the weaknesses of existing international regulations governing global health – and to adopt a new legal instrument at the Seventy-seventh World Health Assembly in May 2024. However, Member States were not able to successfully conclude the negotiations. Between late 2021 and May 2024, an Intergovernmental Negotiating Board (INB) had been working on finding a post-COVID-19 consensus on a long list of issues related to pandemic preparedness, surveillance and response. Yet, the high hopes of many WHO Member States as well as non-state actors had given way to sober realism. The failure to reach a consensus, and to do so by the planned deadline, which was very ambitious, can be interpreted in various ways. From the point of view of diplomatic efforts as an “investment”, these efforts may be framed as a “waste of time”. From the perspective of substantial controversies, the decision to prolong the debate may allow for the necessary space to adopt a widely endorsed international agreement.

One of the most contentious issues on which Member States were, up to the very last minute, not able to reach consensus concerns international rules on critical health data, namely the ways in which such data is shared and accessible and the profits and benefits that may be reaped from their use. This policy brief discusses diverse and multiplying policy frames that have influenced and continue to influence the international debate on health data sharing as well as discussions on health data within the WHO. The analysis is based on an extensive study on the emergence and diffusion of policy frames in global health starting in the mid-1990s. Pointing to the growing politicisation and polarisation in health data debates overall – with significant potential for incompatibilities and collisions between normative beliefs and legal rules, this policy brief elucidates why the negotiations on the Pandemic Agreement have been a particularly hard case for international cooperation. Over time, perspectives and positions from low- and middle-income countries have become more prominent in the debate, emphasising principles of equality and benefit sharing related to health data. This finding is mirrored in the fierce political struggles over health data norms and rules in the negotiations on the Pandemic Agreement.

Background

When in late 2021, a new SARS-CoV2 Omicron variant was detected in South Africa, genomic sequence data was rapidly published. South Africa complied with its obligations to share information and data on a potentially dangerous pathogen – and was maximally sanctioned for its compliance with travel bans and other economically devastating responses. The example aptly illustrates the risks associated with sharing sensitive pathogen data that, from the perspective of global health security, for many should be treated as a global public good. Countries complying with pathogen and data sharing rules but unable to secure access to the benefits generated through the shared pathogens and data, such as vaccines, treatment and diagnostics, learned a particularly painful lesson of failed international solidarity and equity during the COVID-19 pandemic. The repercussions of these lessons learned set the tone for the international debate on a new WHO Pandemic Agreement.

From its inception, international cooperation on global health has been shaped by debates on the appropriate norms and rules on the collection, analysis and circulation of health data. This includes heated discussions of the benefits of biomedical and technological breakthroughs. It is thus hardly surprising that the successful conclusion of the negotiations of the new WHO Pandemic Agreement depends largely on the willingness and ability of WHO Member States to agree on the norms and rules pertaining to the sharing of data and its benefits (i.e., vaccines, diagnostics and medical treatment). We define health data sharing as all forms of harnessing and providing health data for (electronic) exchange in (personalised) health care, public policy and science. Health data sharing encompasses pathogen-related data, of which genetic (sequencing) data is the most politicised form of health data that can also generate enormous revenue (Fortune Business Insights, 2024).

In the eyes of many experts, any half-baked decision on these substantial issues, no matter if the premature adoption of an unfinished legal instrument (Wenham et al., 2022; Wenham & Eccleston-Turner, 2024) or the continuation of what may become a never-ending drafting process, may miserably fail the intended goal of finding appropriate, effective and equitable international responses to future pandemics. During the negotiations, it has become apparent that improving pandemic preparedness, prevention and response is surrounded by major controversies reflecting historically evolved geopolitical conflicts and the growing voice and weight of Member States that have been considered peripheral to the global health system, especially its economic dimension.

The matters of pathogen access and benefit sharing have revealed great potential for conflict. Pathogens are microorganisms that can potentially cause diseases. Knowledge about pathogens and access to pathogen-related data are seen as the linchpin for pandemic prevention, preparedness and control – and constitute a precious public good that can be easily turned into a bargaining chip and commodity. Pathogens constitute the most important material resource in research and development for pandemic preparedness and control. The data associated with pathogens and derived from their analysis constitutes the most important immaterial resource. It is, before all, the circulation of these immaterial resources that causes much controversy over the commodification and market value of such data. Effective international pandemic governance thus depends on the possibility to find a middle ground between incentivising benefit sharing while safeguarding the value of pathogen-related knowledge as a public good. The proposed WHO Pathogen Access and Benefit Sharing (PABS) System is at the very core of the discussions.

This policy brief highlights the enduring challenges that have shaped the pandemic negotiations and that will likely stay around for a considerable time. It provides a historical analysis of the most contentious policy frames surrounding

the access to, sharing of and use of health-related data. Frames, most generally, place policy issues in a specific context and emphasise certain aspects of a political problem while de-emphasising others (Goffman, 1974). The transnational circulation of health data, for example, can be framed as an indispensable practice for medical progress – or it can be framed as an infringement on individual self-determination and personal safety. The way in which actors frame issues thus has a significant effect on the dynamics of political debates. At the same time, policy frames are dynamic artefacts that change with the outcome of policy negotiations and discussions. We analysed the emergence and diffusion of policy frames as they appeared and circulated both in public debate (explicitly newspapers) as well as in intergovernmental bodies of international organisations beginning in the year 1995. For example, the WHO recognised the sharing of health data as a human rights issue back in the early 2000s and therefore focused in its debates on data protection issues. Over the past few years, this framing has gradually been contested – not only by private actors advocating for a liberalisation of the use of data and of pathogens, but also by actors from low- and middle-income countries (LMICs) claiming to be left out of transnational discussions and decision-making on the sharing of health data. As a general trend, frames surrounding human rights – for instance addressing privacy and data anonymisation – have been identified as having the greatest disruptive potential and leading to strong contestation over time.

By showing which policy frames have influenced international debates on health data sharing and how they have evolved over time, this policy brief exposes the negotiations on the Pandemic Agreement as a particularly hard case for international cooperation. Why have contested policy frames regarding health data sharing evolved into a major bottleneck towards a more effective and legitimate global system for pandemic preparedness, prevention and response? And what are the chances that the new Pandemic Agreement –

should it ever materialise – reflects perspectives and positions of actors from LMICs on access to health data and benefit sharing, potentially contributing to greater equity in global health?

COVID-19 as a window of opportunity to re-negotiate international health law

In May 2021, the European Council adopted a decision to support the launch of negotiations on the international Pandemic Agreement. A great many state and non-state actors seized this exceptional window of opportunity with the aim of significantly re-writing international health law. Global health as a policy field is regulated by very few legally binding international agreements. These include the International Health Regulations of 2005, a WHO regulation to prevent and control cross-border disease outbreaks, and the TRIPS agreement, a minimum standards agreement on the trade of intellectual property (Walckiers et al., 2024). Steven Solomon, the head of WHO's legal department, emphasised that an efficient system for pathogen access and benefit sharing is one of the core areas for successful pandemic negotiations (Mersh, 2023). Establishing a link between the generation and transfer of data and the equitable enjoyment of the knowledge obtained from the data thus constitutes an innovative *quid pro quo* formula.

The intended formula of the Pandemic Agreement aims to offer a mixture of binding and non-binding provisions. It is aligned with international norms and principles on human and privacy rights, trade, biodiversity and climate change, integrating different areas of international law into a single global health agreement. Among the many issues discussed in the context of amending international health law, the question of access to health data and the sharing of its benefits stands out as the issue with the greatest transformatory potential and is thus a point of fierce political contention, as the discussions on the WHO PABS System have revealed. The PABS System draws on WHO's Pandemic Influenza Preparedness Framework, a

non-binding legal framework adopted in 2011. Despite emphasising access over benefits in its language, the Pandemic Influenza Preparedness framework offers a benchmark, especially for Member States of LMICs, to circumvent the potential trade-off between providing access to pathogens and receiving equitable and fair benefit sharing. The goal of such a system is to make sure that data about new pathogens is shared while ensuring equitable access to the benefits. Discussions inside and outside the Inter-governmental Negotiating Board (INB) make it clear that pathogen access and benefit sharing have become the focal point of deliberations not only regarding effective pandemic governance, but also with regards to the recognition of core international norms of equity, solidarity and international assistance. In essence, to reach equitable access to pandemic countermeasures (most notably vaccines), high-income countries (HICs) must be ready to waive intellectual property rights, while LMICs must be willing to share crucial data (pathogen and genomic) and other information (Switzer et al., 2024).

In the Pandemic Agreement negotiations, the Group of Equity (an amalgamation of 29 LMICs) and the PABS Coalition (a collaboration of the Group of Equity and the African Union) urged for increased multilateralism based on the principles of accountability and benefit sharing. Lines of conflicts on the Pandemic Agreement were especially evident between the US – favouring stronger protections of pathogen patents – and the UK – demanding anonymous sharing of health data – on the one hand and the Group of Equity and the PABS Coalition on the other. The latter advocacy coalitions argued, among other things, that “anonymous usage cannot serve the purposes of public accountability and vigilance” (Ramakrishnan, 2024), but rather that anonymity can indeed be detrimental to benefit sharing in global health. On another note, the Africa Group mentioned that the politics of knowledge must work both ways, i.e., to prevent future pandemics. This means that all types of knowledge must be taken into consideration in global health law.

Discussions on the lack of transparency and timely legislation are not new to global health. As examples such as the Global Initiative on Sharing All Influenza Data and the negotiations on the PABS System highlight, these challenges have become more pressing than ever in recent years. In a multilateral agreement of the magnitude of the envisaged Pandemic Agreement, the assumption that increased access to health data automatically leads to more benefit sharing and equity in health becomes a fallacy. One reason for this is that controversies over human and personal rights, such as privacy and consent, as well as over the commercialisation of pathogens have not yet been fully reconciled. Moreover, access to data does not automatically imply that this data and the knowledge gained from it are equally beneficial for all countries.

Pandemic preparedness and control depend, to a large extent, on the ability of multilateral institutions to have access to and benefit from “scientific research and data” that can then inform decision-making and rule implementation (McInerney, 2024). The prospects for eventually adopting a Pandemic Agreement in the future depend on WHO Member States’ ability and willingness to find a compromise on the crucial issue of health data sharing. Health data and its derived knowledge stand out as the most precious resource – both in terms of lifesaving and profitability – that WHO Member States are debating. As controversies between WHO Members States with strong pharmaceutical industries, typically located in a few HICs, as well as some LMICs, persist, many observers fail to see constructive solutions that consider the diametrical standpoints, even in the case that Member States resume their negotiations. Yet, how exactly are controversial viewpoints that have informed debates on the sharing of health-related data for decades reflected in the negotiations on the Pandemic Agreement?

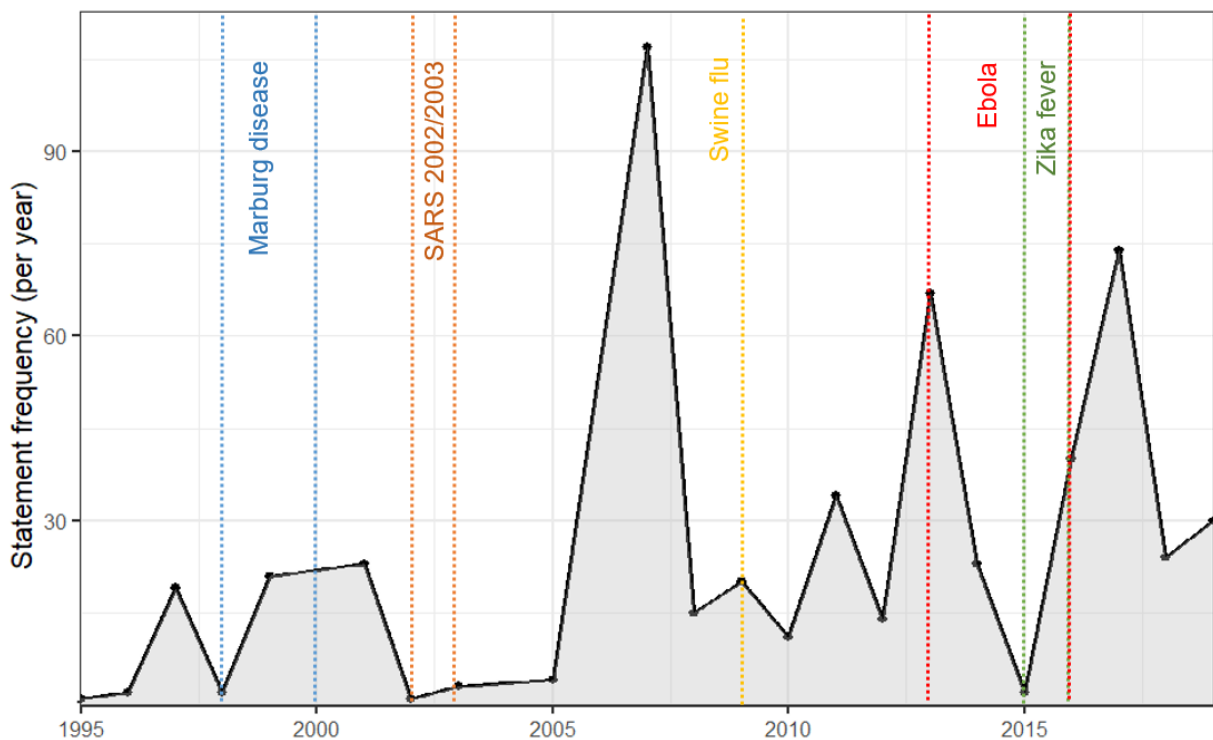
The Pandemic Agreement and the history of debates on health data (sharing) in global health governance

From a historical perspective, insights from the INB discussions leading right into “adoption failure” are a logical outcome of decades of political struggle over the use and sharing of health data. These struggles expose, in the first place, that knowledge and data policies constitute the core of global health governance and norm-setting. There is a long-standing trend in global health governance that discussions and negotiation processes have – for the most part – evolved around regional interests, thereby mirroring geo-political power dynamics, partially historically grown. While all global health actors – at least in some way – consider the sharing of health data as fundamental for the improvement of global health and the realisation of universal health care, only a few actors dominate the

framing of this policy field, in particular international organisations such as the WHO and corporate non-state actors. Civil society, on the other hand, is rather absent in official public and expert debates.

Contrary to the developments during the COVID-19 pandemic, other epidemic and pandemic outbreaks of infectious diseases since the mid-1990s did not have such a strong impact on discussions on health data (sharing), benefit sharing and data-based knowledge production, particularly in international organisations as Figure 1 highlights. Technological progress rather than disease control or global health security concerns has fuelled the framing of this policy issue. Several WHO experts confirmed in interviews that developments in the production, dissemination and sharing of health data have been incentivised on an irregular basis especially by corporate and philanthropic donors and collaborators in the past two decades.

Figure 1: Statements per year regarding discussions of health data sharing in international organisations



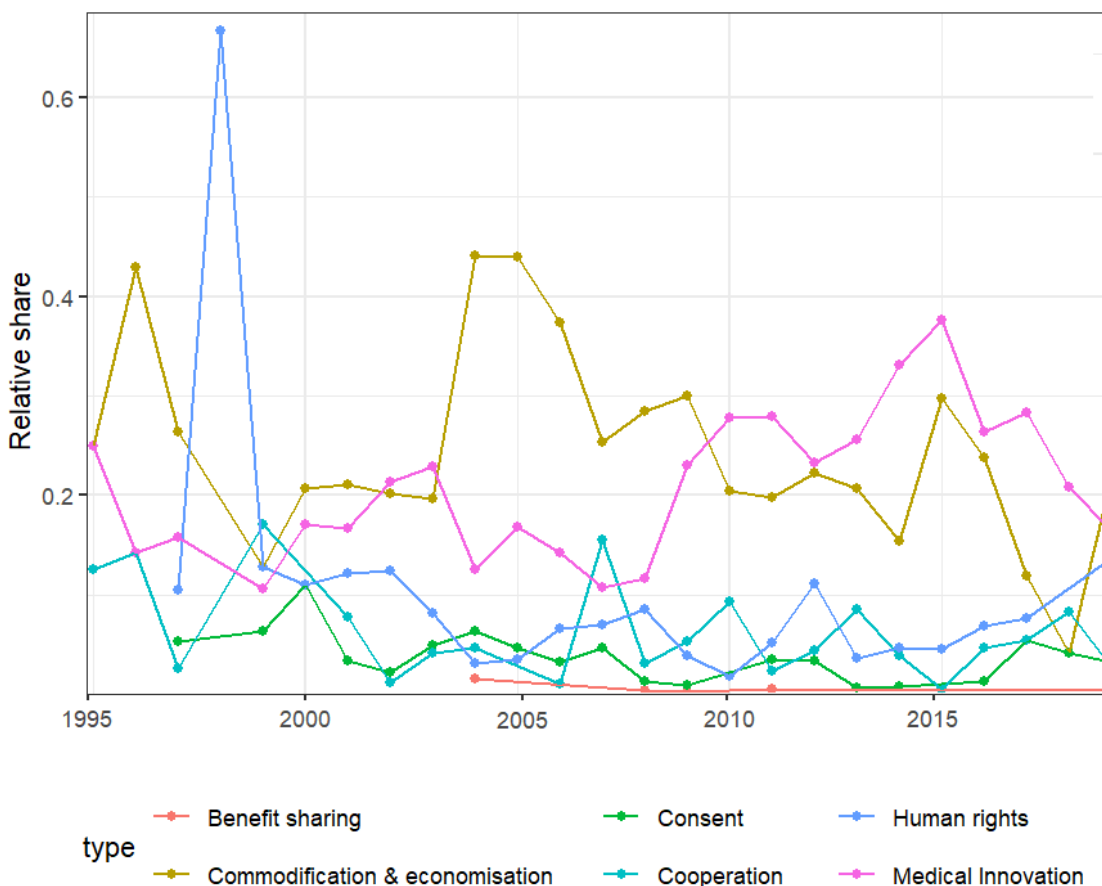
Source: Authors

Additionally, our longitudinal study reflects that the sharing of health data is more likely to be addressed in the context of other health-related policy fields, like telemedicine, or in discussions on regional and international frameworks, like the General Data Protection Regulation, instead of being treated as a separate agenda item in global health governance. This has changed with the COVID-19 pandemic and the PABS System negotiations that are determined by WHO Member States and their representatives. The INB was created as an intergovernmental negotiating body representing and upholding the interests of all WHO Member States. However, it remains questionable to what extent different perspectives on health data and their benefit sharing can be equally considered and included in a multilateral pandemic agreement.

To strengthen their position, Member States with geographic and political ties have formed advocacy coalitions, such as in the case of the Group

of Equity. Such advocacy coalitions, particularly those encouraged and dominated by state actors from LMICs, are a rather new phenomenon in the discussions on the sharing of health data and data-based knowledge, especially on this scale. This allows for two possible conclusions. First, there have been increasing attempts in recent years to decolonise global health by LMICs. In the negotiations on the Pandemic Agreement, we observed a culmination of the demands for a decolonial reform of global health and international health law (Phelan & Sirleaf, 2023). Second, and strongly tied to the problem of being excluded, unlike other disease outbreaks in the past several decades, COVID-19 has been unique in terms of its magnitude, including mortality rates and the number of global infections. This emphasised the urgency for better and more equal global health protection and likewise revealed the inefficiency of current international health law in times of crises (Lazarus et al., 2024).

Figure 2: Relative share of selected frames between 1995 and 2019 in the debate on health data sharing



Source: Authors

As Figure 2 highlights, policy frames have increasingly diversified over time between 1995 and 2019. Following Entman (1993), frames are defined by one, several or all of the following four components: problem definition, treatment recommendation, causal interpretation and moral evaluation. Hence, the analysis only includes statements that either define a problem, provide a solution, reflect on how health data (sharing) connects to and is influenced by other policy issues, or make a normative claim on the topic. As shown in Figure 2, human rights issues have particularly dominated the discussions on the sharing of health data between 1995 and 2000. Policy frames on benefit sharing and equity related to health data, though, have only become more prominent in recent years, leading to a politicisation regarding justice and equity (Ndumbe-Eyoh et al., 2021). Before 2020, as the policy frame analysis highlights, benefit sharing was one of the less discussed frames – and before 2004, it was even a non-issue in global health.

Generating health data and providing equal access to it has been increasingly perceived to be a crucial factor for knowledge production in global health and the establishment of a truly global health infrastructure. Sharing critical health data across borders is thus likewise recognised as a prerequisite for reaping the benefits of (bio-)medical and technological progress worldwide, especially in times of health crises. While the pandemic intensified discussions around the sharing of health data, contentious dynamics emerged even before the outbreak of COVID-19, especially when data crossed national borders or was shared between private and public actors, HICs and LMICs, as well as between state and non-state actors.

Although a broader consensus exists particularly on stricter access to health data and the overwhelming benefits of this data to individual and population health, numerous challenges persist, including questions of how to deal with financial shortages and the lack of public health infrastructures. As a result, the economisation and

innovation frames (Figure 2) have become more dominant since 2010.

LMICs are often portrayed as suffering from financial, medical knowledge and human resources scarcity, in need of support from European countries and the United States to catch up on (bio-)medical and technological developments and thus to become better equipped for (up-coming) epidemics and pandemics. Similarly, over the past few decades, more and more efforts have been made at the international level to implement ethical standards for the collection and preservation of pathogens and associated data. One such aim is to prevent the potential abuse of low-income countries as testing grounds for clinical trials. International legislation on this policy issue, though, is still insufficient to date, presenting the development of a new pandemic agreement as a window of opportunity to remedy legal gaps and loopholes in international health law.

Recommendations

Based on the above analysis and considering the open-ended nature of the policy debate targeted in this brief, the following recommendations on policy options seem plausible.

Given the divisive nature of international negotiations on intellectual property, knowledge production and sharing across borders, it is necessary to acknowledge that these questions cannot be thought of as independent of fundamental questions of institutional reform and shifting geopolitical weight and alliances. Any attempt to make global health institutions more legitimate from the viewpoint of countries that have borne the brunt of past pandemics will hinge on a deep transformation of the norms and rules governing the production, sharing and benefits of health knowledge and data. It is unsurprising that the many countries disappointed with the power imbalances marking discussions on intellectual property rights at the World Trade Organization would want to see the WHO becoming more authoritative in this field.

The impasse in the negotiations on the Pandemic Agreement can be presented as an indicator of politicisation and lack of compromise – or it can be taken to reflect changing power constellations within the WHO, the growing voice of countries formerly at the margins of global health governance and an ongoing pluralisation of perspectives on global health. In fact, successful adoption of a broadly endorsed agreement (and, in the best of cases, further and more concrete amendments to such an agreement) could serve as a blueprint for norm setting on other global health threats such as antimicrobial resistance.

Many observers of the INB negotiations concluded that, apart from the political struggles discussed in this policy brief, WHO Member States had already come quite far in agreeing on a number of core principles that should inform the new Pandemic Agreement, including equity. It is, thus, very likely that a future pandemic agreement will reflect the collective desire to address the wider social, political and economic determinants of pandemics and to integrate a great number of principles and norms (e.g., equity, non-discrimination, human rights, sovereignty, solidarity, transparency and many more) into a single legal instrument. However, it is yet to be seen to what extent an agreement on these larger principles can remedy the deficiencies of a weakly legalised and strongly asymmetrical global health system without clear, unambiguous binding rules on pandemic preparedness and control. As we have seen with so many treaties before, the adoption of an agreement is one thing, ratification, implementation and compliance are another. In any case, a new pandemic agreement could become a powerful instrument in the hands of advocates for equity, human rights and access to medicines to hold governments accountable for their actions.

Germany, as a country that has been for considerable time a backbone of global health institutions and the WHO, in particular, must keep its commitment to negotiating the “beef” issues (e.g., PABS System, financing and intellectual

property) in any new attempt to finalise the negotiations. Germany should also use its powerful position within the European Union to reduce resistance to stronger international legislation on intellectual property, technology transfer and benefit sharing. Policy solutions, such as the Medicines Patent Pool (MPP) established by Unitaid in 2010, would be a feasible step in this direction. In the MPP, countries hosting vaccine-manufacturing firms that have received public funding would require such firms to make patents available to these patent pools. An important dimension of international cooperation such as the MPP, is the active transfer of knowledge and technology, rather than just the sharing of biochemical formulas (Gore et al., 2023).

From the point of view of efficient and successful diplomacy, WHO Member States have clearly missed a window of opportunity to potentially strengthen the WHO’s authority in the aftermath of the COVID-19 pandemic. However, the verdict of “failure” may not be shared unequivocally, as LMICs with limited delegation capacity will be given more time and space to “engage in meaningful dialogue and collective strategizing” (Sekalala et al., 2024). Advocates of extending equity concerns to the process of negotiating a new pandemic agreement argue that “to design a treaty that delivers fair outcomes, attention must be given to both the process and the results” (Sekalala et al., 2024). In the face of the looming second Trump presidency and other potential changes to geopolitical constellations, though, it is unclear if prolonged negotiations will enhance procedural and time equity for LMICs.

On the basis of a universally shared belief that health data sharing is existential for pandemic preparedness and response, countries with strong health economies must play a constructive role in addressing major concerns over profit and nationalism voiced by those who were last in line to benefit from the medical breakthroughs generated through this data.

Conclusion

Debates on profound issues of inequality, solidarity and truly global cooperation in pandemic times have now boiled down to a four-letter acronym – PABS, a mechanism that has been discussed as a technical solution to fix unequal suffering and access to life-saving treatment resulting from extremely asymmetrical interdependence between HICs and LMICs. At the same time, though, formal discussions in the INB and informal talks accompanying them exhibited the magnitude of the politics of knowledge and of health data that stand in the way of effective and

legitimate global health governance, including the very legitimacy of the WHO in the eyes of many disillusioned LMICs. The timely finalisation and adoption of the Pandemic Agreement has failed precisely for these deep-seated geopolitical tensions that render international cooperation during health emergencies so difficult. Even if a new pandemic agreement were to be adopted at some point, it may be an agreement devoid of any sea change in the way WHO Member States share and use health data and information – thus offering limited hope for better cooperation and greater equity during future pandemics.

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