

## Norm Conflicts in Global Health: the Case of Indonesia and Pandemic Influenza Preparedness

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## **Norm Conflicts in Global Health: The Case of Indonesia and Pandemic Influenza Preparedness**

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# Norm Conflicts in Global Health: The Case of Indonesia and Pandemic Influenza Preparedness

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## ABSTRACT

The current Covid-19 pandemic highlights the importance of international cooperation in the prevention and containment of infectious diseases. This is true for all pathogens with pandemic potential, including certain influenza viruses, which is why the World Health Organisation (WHO) has maintained a system for monitoring and sharing influenza viruses for decades. In 2007, Indonesia rescinded its cooperation in this system even though experts ascribed a crucial role to Indonesian virus samples in the prevention of a flu pandemic; such a pandemic was at the time feared to be imminent. Indonesia's policy was nurtured inter alia by a growing frustration with inequalities in the existing system in which industrialised countries as well as drug and vaccine producers benefitted from samples provided by countries of the Global South but did not share these benefits adequately with those countries. The new "Pandemic Influenza Preparedness Framework", concluded in 2011, established benefit-sharing and virus-sharing as principles on an equal footing. It thus reformed the WHO process but also brought to the fore existing tensions and conflicts between various norms and practices: global health cooperation (which requires the sharing of pathogen samples), the protection of intellectual property rights (which is intended to promote innovation and ensure profits), and the protection of genetic resources (which considers pathogens as national resources and requires adequate benefit-sharing in their exploitation). This Working Paper traces Indonesia's policy regarding pandemic influenza preparedness and the reform process within WHO. Moreover, it presents the interlinkages between said norm complexes, which are exacerbated by technological developments in genetic sequencing, as areas that would merit further theoretical and empirical research.

## ZUSAMMENFASSUNG

Die aktuelle Covid-19-Pandemie demonstriert eindrücklich die große Bedeutung internationaler Zusammenarbeit bei der Vorbeugung und Eindämmung von weltweiten Krankheitsausbrüchen. Dies gilt für alle Erreger, die Pandemien hervorrufen können – einschließlich bestimmter Varianten des Influenzavirus. Deshalb unterhält die Weltgesundheitsorganisation (WHO) seit Jahrzehnten ein Netzwerk, innerhalb dessen Influenzaviren beobachtet und zu Forschungszwecken weitergegeben werden. 2007 kündigte Indonesien seine Mitwirkung in diesem System auf, obwohl indonesische Virenproben als wesentlich für die Abwendung einer befürchteten Grippe-Pandemie galten. Dahinter stand unter anderem eine wachsende Frustration mit Ungleichheiten innerhalb des Netzwerks, in dem Industrieländer und große Pharmakonzerne von Virenproben aus Ländern des Globalen Südens profitierten, ohne dass letztere an den Profiten angemessen beteiligt wurden. Der 2011 vereinbarte „Pandemic Influenza Preparedness Framework“ (PIP Framework), der „benefit-sharing“ als gleichberechtigtes Element neben „virus-sharing“ etablierte, reformierte zwar die internationale Grippebekämpfung, verschärfte aber auch bestehende Spannungen und Konflikte zwischen verschiedenen Normen und Praktiken: der globalen Gesundheitszusammenarbeit (die den Austausch von Erregerproben erfordert), dem Schutz geistigen Eigentums (der Innovation fördern und Profite sichern soll) sowie dem Schutz genetischer Ressourcen (der

Erreger als nationale Ressource betrachtet und bei ihrer Ausbeutung angemessene Profit-Beteiligung fordert). Dieses Working Paper zeichnet Indonesiens Politik zur Grippe-Pandemievorbereitung und den Reformprozess innerhalb der WHO nach. Es markiert außerdem die genannten Normkomplexe sowie die Rolle technologischer Neuerungen in der Gensequenzierung darin als künftige empirische und theoretische Forschungsfelder.

### **Addendum**

*Sometimes research papers are being overtaken by real-life events. By the time this Working Paper went into the editing process, SARS-CoV2 had only just begun to spread outside China. At the time of publication, the WHO had declared the outbreak a pandemic and the virus had spread all over the world. These developments emphasise how important international health preparedness and cooperation are, and how right those experts were who warned that a pandemic might occur at any time. Influenza used to be considered the most likely causative pathogen and was hence at the centre of international pandemic preparedness efforts (and of this paper). In light of the current events, this may well change. Now is the time for emergency response. But the time will come for considering lessons learned, both practically and academically. It will then also be possible to analyse whether and how the norm conflicts that have emerged over pandemic influenza preparedness, as outlined in this Working Paper, have played out in the Covid-19 pandemic as well and what implications this might have.*

*Manchmal werden wissenschaftliche Texte von realen Ereignissen überholt. Als dieses Arbeitspapier in die redaktionelle Bearbeitung ging, hatte SARS-CoV2 gerade erst begonnen, sich außerhalb Chinas zu verbreiten. Zum Zeitpunkt der Veröffentlichung hatte die WHO den Ausbruch bereits zur Pandemie erklärt, und das Virus hat sich auf der ganzen Welt verbreitet. Diese Entwicklungen unterstreichen, wie wichtig die internationale Gesundheitsvorsorge und -zusammenarbeit sind und wie recht diejenigen Expertinnen und Experten hatten, die davor warnten, eine Pandemie könne jederzeit auftreten. Influenzaviren galten bislang als wahrscheinlichste Auslöser und standen daher im Zentrum der internationalen Pandemieprävention (und dieses Papiers). Angesichts der aktuellen Entwicklungen dürfte sich das ändern. Jetzt ist zunächst die Zeit für Krisenreaktion. Aber die Zeit wird kommen, in der Lehren aus dem Geschehen gezogen werden können, sowohl aus praktischer als auch aus akademischer Perspektive. Dann kann auch untersucht werden, ob und, wenn ja, wie sich die hier beschriebenen Normenkonflikte um die Grippe-Pandemieprävention auch in der Covid-19-Pandemie niedergeschlagen haben und was daraus zu folgern ist.*

### 1 INTRODUCTION<sup>1</sup>

The emergence of a novel Corona virus (SARS-CoV-2) – which has been spreading rapidly all over the world – highlights the importance of international cooperation and the timely

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<sup>1</sup> This paper presents a revised and updated version of a case study (Becker-Jakob 2014) prepared for the PRIF research project "'Rogue States", "Outlaws", and "Pariahs": Dissidence Between Delegitimation and Justification", directed by Klaus-Dieter Wolf and funded by the Deutsche Forschungsgemeinschaft (DFG) (<https://www.hsfk.de/en/research/projects/rogue-states-outlaws-and-pariahs-dissidence-between-delegitimation-and-justification/>, 12.12.2019). See also Gertheiss et al. 2017. The author is grateful to Melanie Coni-Zimmer for very helpful and constructive comments on a draft version of this paper.

sharing of relevant information for global health preparedness and the containment of pandemics. The fact that Chinese scientists quickly sequenced the genome of SARS-CoV-2 and shared pertinent information publicly has allowed experts elsewhere to carry out important research on their own (see e.g. Cohen 2020; Yong 2020).

Just like Corona viruses, influenza viruses can harbour pandemic potential, as proven by the Spanish Flu in 1918/1919, the Hongkong Flu in 1969, or the swine flu pandemic in 2009 (see Fineberg 2014).<sup>2</sup> Experts estimate that influenza pandemics are likely to occur at least two to three times per century. Preventing such pandemics is high on the list of priorities in global health policy (see e.g. WHO 2016; WHO 2019a). In the early 2000s, a series of serious outbreaks of avian influenza occurred in South East Asia, and experts feared that these might develop into a flu pandemic. These concerns notwithstanding, Indonesia in 2007 unilaterally abandoned the decades-old global practice of sharing flu virus samples with other countries and the World Health Organisation (WHO), and demanded a far-reaching reform of the existing cooperation in influenza preparedness. Indonesia's policy compelled the reluctant countries of the Global North to enter negotiations on a new normative and operational framework in which viruses as well as the benefits arising from their use in research and industry would now be shared on an equal footing. These negotiations resulted in the 2011 Pandemic Influenza Preparedness Framework (PIP Framework). The process never left established international institutions, namely the WHO, and Indonesia mostly employed traditional negotiation tactics. However, the circumstances under which these events took place – including the tangible risk of a global health crisis – rendered Indonesia's policy a remarkable act of dissidence in international politics (see Gertheiss et al. 2017).

This policy altered the practice of influenza virus-sharing and established benefit-sharing as a new principle in this policy field. The process and discourse it triggered have tied in with normative developments outside the realm of global health, such as access and benefit-sharing under the Convention of Biodiversity (CBD), intellectual property rights, and the protection of genetic resources. The ensuing conflicts between countries of the Global North and South, in turn, have strong implications for virus-sharing and influenza preparedness: Origin countries of virus samples, often located in the Global South, have long demanded a fair share of the benefits accruing from the commercial use of samples gathered on their territories; at the same time, Northern countries and companies have referred to intellectual property rights to protect their products and gains. The protection of genetic resources, as codified in the 2010 Nagoya Protocol to the CBD, is now widely being interpreted to include pathogens as genetic resources. In fact, Indonesia's claim to 'viral sovereignty' during the PIP Framework negotiations arguably helped pave the way for this interpretation.<sup>3</sup> This claim, however, can easily conflict with the requirements of rapid and free pathogen-sharing for global health preparedness and response, especially in global health crises (see e.g. Halabi 2019; Srinivas 2017; WHO 2016).

This Working Paper first describes the history of pandemic influenza preparedness in the WHO. It then recounts the process that led to the renegotiation and reform of the existing system, portrays Indonesia's role and strategy in this process and presents the arguments employed by its critics and supporters. In the subsequent section, the paper places these developments in the context of norm conflicts in the areas of global health, intellectual property rights, access and benefit sharing, and the protection of genetic resources. It

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2 A pandemic is an outbreak of an infectious disease in several regions of the world at the same time, with the potential to spread all over the world. An epidemic is a regional outbreak. Pandemic influenza is distinct from the seasonal influenza outbreaks that occur annually.

3 'Viral sovereignty' represents the assertion that viruses isolated from a given territory are the property of the country of origin (Halabi 2019: 114; see also Hameiri 2014).

shows that the negotiations for the PIP Framework, though seemingly confined to a narrow issue area, are actually embedded in a much broader complex of political and normative tensions – a case in point being the conflict between the protection of genetic resources and ‘viral sovereignty’ on one hand, and the recognised need for the sharing of virus samples to prevent the spread of infectious diseases on the other. The Working Paper concludes by outlining areas for future theoretical and policy-oriented research regarding these norm conflicts, the role of technological developments in genetic engineering in this policy field, and the implications for politics in other areas.

## 2 THE HISTORY OF INTERNATIONAL COOPERATION IN INFLUENZA PREPAREDNESS

Ever since its foundation in 1946, the WHO has worked for the improvement of global health and the fight against infectious diseases. Based on these goals and on the WHO Constitution, a system of global health governance has emerged that includes various initiatives targeted at specific global health problems. Since the 1950s, one such initiative has been aimed at containing the effects of influenza outbreaks and at preventing the emergence of influenza pandemics. World health experts have repeatedly argued that one of the biggest threats to global health might emanate from a new influenza pandemic (see Elbe 2010: 479).<sup>4</sup> Such pandemics occurred repeatedly throughout history. In the 20th century, the Swine Flu in 2009, the Hong Kong Flu in 1969, the Asian Flu in 1957 and, most notoriously, the 1918 Spanish Flu claimed between several hundred thousand (2009) to over 50 million (1918) lives worldwide (see Saunders-Hastings/Krewski 2016; WHO 2019: 2). Given the conditions in the modern globalised world, the accelerated and increased international traffic in particular, future influenza pandemics could spread even more widely and rapidly than previous ones and could have severe public health, economic and security implications (see e.g. Saunders-Hastings/Krewski 2016; WHO 2019: 2).

International cooperation in pandemic influenza prevention is necessary not only because infectious diseases do not respect borders. Specifics of the influenza virus make close cooperation all the more important. Flu viruses are endemic in almost all regions of the world. They are highly variable, which means they can change their genetic structure relatively rapidly, and therefore require constant monitoring and regular adaptation of drugs and vaccines so that timely protection and remedies can be provided. In addition, the viruses can change their target groups: for instance, certain variants of the swine flu (H1N1) and bird flu (H5N1, H7N9) have jumped species and are now able to infect humans. Depending on the specific strains, the viruses can be easily transmitted and can be dangerous for humans, which renders them a great risk for world health and one of the priorities of global health surveillance and promotion (see WHO 2019).

Since 1952, international cooperation in influenza preparedness has been institutionalised in the WHO Global Influenza Surveillance Network (GISN) which was renamed Global Influenza Surveillance and Response System (GISRS) in 2011.<sup>5</sup> GISRS currently comprises institutions in 115 WHO member states, including National Influenza Centres in all regions of the world, six WHO Collaborating Centres in Australia, China, Japan, the UK and the USA, as well as several Reference and Essential Regulatory Laboratories. The Centres and laboratories are all part of national government or research institutions. GISRS inter alia acts as monitor for detecting novel influenza viruses including those with pandemic potential,

4 For an analysis of the “securitization of H5N1” as a “pressing existential threat demanding an urgent and sustained international response” see Elbe 2010.

5 On this and the following see [https://www.who.int/influenza/gisrs\\_laboratory/en/](https://www.who.int/influenza/gisrs_laboratory/en/) (02.02.2020). See also Al-Tawfiq et al. 2014.

and it also provides data upon which the WHO issues its annual recommendations for the composition of the vaccines against seasonal flu. Vaccine manufacturers can then use the information generated through GISRS to develop seasonal flu vaccines, drugs and other products.

For decades, the member states of GISN cooperated relatively smoothly within the network and with external partners, including vaccine manufacturers (see Kamradt-Scott/Lee 2011: 834). Relevant virus strains were collected in their countries of origin and passed to “specialized laboratories of other states participating in GISN, for both diagnostic and risk-assessment purposes, and to encourage the development of new vaccines for the subsequent influenza season” (Vezzani 2010: 677). Rules for the transfer of virus samples and regulations about passing these samples to third parties were under-developed until 2005, when the WHO issued guidelines for the sharing of pandemic influenza viruses. These guidelines posited that any transfer of virus samples to entities not participating in GISN would require the consent of the state of origin (Vezzani 2010: 677). Yet, the guidelines were not legally binding. Simone Vezzani describes the state of play in the mid-2000s as follows:

“As a matter of fact, viruses are commonly transferred by GISN laboratories to drug companies, which use them to manufacture vaccines and other pharmaceuticals without assuming significant, if any, benefit-sharing obligations. In addition to this, it is not unusual for both GISN laboratories and third entities to make intellectual property rights (IPR) claims over products (genes and gene sequences, vaccines etc.) or medical technologies based on pathogen samples shared through the network” (Vezzani 2010: 677).<sup>6</sup>

These pathogen samples often stemmed from countries of the Global South, whereas the vaccine producers were mainly located in industrialized countries, and “[u]ntil quite recently, interest in the [GISN, UJ] was generally limited to industrialized countries whose populations used seasonal vaccines” (WHO n.d.: 1). The annual adaptation of existing drugs and vaccines as well as the development of new ones benefitted greatly from the virus- and data-sharing practices established under GISN. At the same time, there had been longstanding and wide-spread discontent in the Global South with existing global structures of drug and vaccine accessibility and distribution, and with the exploitation of natural and genetic resources in general (Wolf/Scholz 2017; see also Elbe 2010: 480; Hammond 2009). Nevertheless, GISN did not receive much public or professional attention (see Hammond 2009).

This changed drastically in the mid-2000s when experts became increasingly concerned about a possible new flu pandemic. Indonesia had been critical of GISN’s functioning and in particular the “high price of patented antiviral drugs [...] produced by foreign pharmaceutical companies” for some time (Vezzani 2010: 677). In 2007, it cancelled its cooperation in GISN and ceased to share the circulating virus strains which caused severe H5N1 outbreaks in birds and humans in the region. This step provoked strong criticism and caused intense debates within the WHO system. However, the Indonesian withdrawal from GISN also resulted in a negotiation process for a reformed international framework for influenza preparedness, and in the 2011 PIP Framework. Moreover, through Indonesia’s argumentation and actions, virus-sharing became intertwined with other regimes such as access and benefit-sharing, intellectual property rights, and the protection of genetic resources.

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6 In sharper words, Edward Hammond characterized GISN as “global virus vacuum” which, in the guise of international global health cooperation under WHO aegis, mainly served the Northern pharmaceutical industry (Hammond 2009).



### 3 THE CRISIS OF INFLUENZA VIRUS-SHARING

#### 3.1 *The Role of Indonesia*

In the mid-2000s, worries increased that a new influenza pandemic might be imminent due to severe outbreaks of bird flu, caused by a highly pathogenic H5N1 influenza strain, in several Southeast Asian countries (Elbe 2010: 477). Millions of birds were infected and had to be culled, and these countries also recorded unusually high infection and casualty rates among humans. The WHO assessed the situation at the time as very serious:

“Of all the avian influenza viruses, which normally cause infection in birds and pigs only, the H5N1 strain may have a unique capacity to cause severe disease, with high mortality, in humans.”<sup>7</sup>

While transmission was seen only from birds to humans, fears existed that the H5N1 virus could mutate to enable human-to-human transmission. In this case, experts estimated that millions of people worldwide could be affected by a pandemic. Prior to 2007, Indonesia had provided H5N1 virus samples to several laboratories collaborating in GISN “for diagnostic confirmation and risk assessment purposes” in accordance with established practice (Hammond 2009; Sedyaningsih et al. 2008: 482).<sup>8</sup> Stockpiling and distribution of sufficient doses of drugs and vaccines is one of the crucial elements of pandemic preparedness, and depends on the availability of circulating virus strains (Fidler 2008: 88). The acute fear of a human bird flu pandemic greatly increased the demand for drug and vaccine stockpiles especially in industrialized countries, even though these countries had not yet been affected by outbreaks (see Elbe 2010: 477, 480; Hammond 2009). In 2005, Indonesia had been unable to purchase stocks of a crucial antiviral drug, as “rich countries had already locked up the supply” (Hammond 2009; see also Elbe 2010: 480–481). The limited production capacities were moreover located almost exclusively in the North at the time (see Irwin 2010). All this fostered fears in Jakarta that increased demand and rising prices might block developing countries’ access to the products they needed to contain their regional outbreaks, and for which they had provided the essential viral resources (see Elbe 2010: 480; Fidler 2008: 88; Sedyaningsih et al. 2008: 486). This was considered “unfair” by Indonesia, and “[i]n a global context, Indonesia can be understood as claiming that GISN was in violation of basic principles of distributive justice” (Krishnamurthy/Herder 2013: 277).<sup>9</sup>

Indonesia also complained that

“results of laboratory analyses that involved H5N1 viruses from Indonesia were presented in various international meetings without prior permission nor notification to the Indonesian government nor its scientists, or with notifications just a couple of hours prior to the presentation, at best.” (Sedyaningsih et al. 2008: 485).

Indonesian government representatives considered these and other related incidents as “unethical practices” that “violated the WHO guidance for the timely sharing of influenza viruses/specimens [...]” (Sedyaningsih et al. 2008: 485).<sup>10</sup> Moreover, towards the end of

7 [https://www.who.int/csr/don/2004\\_01\\_22/en/](https://www.who.int/csr/don/2004_01_22/en/) (02.02.2020).

8 For a detailed account of the H5N1 outbreak in Indonesia and the domestic response to it see Forster 2009.

9 In an analysis from a justice perspective, Meena Krishnamurthy and Matthew Herder dissect the Indonesian normative claims to be based on the values of ownership (of viruses), contribution (to vaccine development and pandemic preparedness), and reciprocity (within GISN and beyond). They argue that if considered in combination, they provide a convincing basis for the Indonesian claim of the injustices of GISN (Krishnamurthy/Herder 2013: 277).

10 The WHO guidance referred to in the quote is the WHO “Guidance for the timely sharing of influenza viruses/specimens with potential to cause human influenza pandemics”, March 2005.



2006 it became known that a pharmaceutical company outside GISN was manufacturing a vaccine based on the Indonesian H5N1 virus strain without having consulted with Indonesia (Molenaar 2010: 44; Irwin 2010; Sedyaningsih et al. 2008: 486). The very fact that a random pharmaceutical company had access to the Indonesian strain without Indonesian consent – albeit not a new phenomenon (Vezzani 2010: 677) – was considered by Jakarta a “violation (again) of the WHO guidance for virus sharing” and “revealed the unfairness and inequities of the global system” (Sedyaningsih et al. 2008: 486). It further increased anger and concern at the fact that the product was too costly to be affordable in sufficient doses for Indonesia (Vezzani 2010: 677–678), especially given the fact that several South East Asian countries were already facing a public health emergency situation due to the regional H5N1 outbreak.

In reaction to these developments, Indonesia refused to share H5N1 virus samples from January 2007 onwards, thus rescinding its cooperation in GISN.<sup>11</sup> Government representatives later described their own action as “drastic” and “inevitable” and cited a “breakdown of trust in the existing WHO GISN and a lack of benefits accruing to developing countries such as Indonesia” as major reasons for its controversial decision (Sedyaningsih et al. 2008: 486).<sup>12</sup>

“Indonesia’s action alarmed the global health community. Indonesia has been hit hard by avian influenza, so its cooperation in tracking the influenza virus (H5N1) was critical. Without access to Indonesia’s influenza strains, global surveillance was jeopardized [...]” (Fidler 2010: 88; see also Elbe 2010: 479; Irwin 2010).

Indonesia connected its withdrawal from GISN with demands for the negotiation of

“a new transparent, fair and equitable, international mechanism in virus sharing, aimed at ensuring fair and equitable access to H5N1 vaccines and other resulting benefits, taking into account the needs of developing countries” (Sedyaningsih et al. 2008: 486).

It did not call into question the basic principle that states should cooperate in pandemic preparedness, but criticized “the unfairness and inequities of the global system” (Sedyaningsih et al. 2008: 486, 487; Vezzani 2010: 677). Jakarta countered the existing cooperation principle with the principle of states’ responsibility for national public health. It also stressed that current virus-sharing practice rested on “responsibilities of developing countries” [to share virus samples, UJ], leaving a big hole in the ‘rights’ of these nations” (Sedyaningsih et al. 2008: 486).

The call for combining virus-sharing with benefit-sharing added a new element to the WHO discussions on pandemic preparedness (Fidler 2008: 89). It mirrored developments in other forums, notably the TRIPS Agreement with the 2001 Doha Declaration, which placed the right to health over intellectual property rights, and the CBD with its ongoing negotiations for a benefit-sharing protocol (the 2010 Nagoya Protocol).<sup>13</sup> Indonesia supported its position with references to the CBD; it claimed that vaccine producers and Northern countries violated the CBD principle of ensuring fair access to benefits arising from the use of

11 For a detailed description of the events from an Indonesian government perspective see Sedyaningsih et al. 2008.

12 Several researchers cite the domestic political situation and government of Indonesia of the time as one contributing factor to the specific, drastic course of action that Indonesia took in 2007 (Curley/Herington 2010:156-160; Hameiri 2014; Irwin 2010). Paul Forster adds the personality of the health minister at the time as one crucial factor among others (Forster 2009).

13 The linkages between these regimes are discussed in more detail in Section 5 of this Working Paper.

genetic resources (Kanth 2013: 15). Jakarta also invoked its right to exercise its sovereignty over genetic resources within its territory, as it saw codified in the CBD (see Fidler 2008: 90; Sedyaningsih et al. 2008: 485; Vezzani 2010: 678). In fact, “Indonesia’s actions introduced the previously unknown concept of ‘viral sovereignty’ to the scientific sharing process. ‘Viral sovereignty’ refers to situations in which countries assert that viruses located and isolated from within their territories are their sovereign property” (Halabi 2019: 114; see also Hameiri 2014).

<b>TRIPS Agreement (1994)</b>	“Agreement on Trade-Related Aspects of Intellectual Property Rights”	WTO agreement, negotiated 1986–94, introduced intellectual property rights into world trade system; provides minimum standards of protection of intellectual property rights and of enforcement among WTO members; <a href="https://www.wto.org/english/tratop_e/trips_e/trips_e.htm">https://www.wto.org/english/tratop_e/trips_e/trips_e.htm</a> .
<b>Doha Declaration (2001)</b>	“Doha Declaration on the TRIPS Agreement and Public Health”	Special Ministerial Declaration adopted by WTO members in November 2001, addresses tension between protection of intellectual property rights and access of less-developed countries to affordable medicines; encourages interpretation of TRIPS that supports states’ right to protect public health; <a href="https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm">https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm</a> .
<b>CBD (1993)</b>	“Convention on Biological Diversity”	3 main objectives: conservation of biological diversity; sustainable use of components of biological diversity; fair and equitable sharing of benefits arising out of the utilization of genetic resources; entered into force on December 29, 1993; 196 parties as of February, 2020; <a href="https://www.cbd.int/">https://www.cbd.int/</a> .
<b>Nagoya Protocol (2010)</b>	“Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Utilization to the Convention on Biological Diversity”	Supplementary agreement to the CBD; provides legal framework for implementation of CBD objective regarding access to genetic resources and benefit-sharing; requires mutual consent in utilization of genetic resources and monetary or non-monetary benefit-sharing; entered into force on October 29, 2014, 123 parties as of Feb. 2020; <a href="https://www.cbd.int/abs/">https://www.cbd.int/abs/</a> .
<b>IHR (2005)</b>	“International Health Regulations”	Purpose: “prevent, protect against, control and provide public health response to international spread of disease”; contains provisions inter alia concerning information sharing, public health measures, national capacity-building, travels and the transportation of goods, and recommendations for disease outbreaks and Public Health Emergencies of International Concern (PHEIC), <a href="https://www.who.int/ihr/publications/9789241580496/en/">https://www.who.int/ihr/publications/9789241580496/en/</a> .

Table 1: Overview of international instruments relevant to pandemic influenza preparedness

Indonesia’s refusal to continue sharing virus samples represented a drastic measure, especially given the perceived imminent risk of a human bird flu pandemic. As of 2010, Indonesia was “the only country that has refused to share virus samples; other developing countries, even those that have supported Indonesia, share their samples without requiring benefits in return” (Fidler 2010: 2). Jakarta’s actions moreover turned a “routine system of

functional public health cooperation” (GISN) into a “heavily politicised North-South issue” (Elbe 2010: 481). As Felicity Nelson states, “Indonesia’s actions in 2007 radically shifted the global mindset; in some countries, the climate of scientific openness gave way to nationalism” (Nelson 2019), but she also emphasises that “Indonesia’s showdown with the WHO did more than just spur patriotic sentiment; it actually pushed the boundaries of international law” (Nelson 2019). However, Indonesia called for the re-negotiation of a collective virus- and benefit-sharing system, aimed to initiate this process through WHO procedures, and introduced concrete proposals as to how the WHO system could be restructured. The Indonesian initiative thus formally remained within the established WHO system and diplomatic discourse.

### 3.2 *Criticism directed at Indonesia’s Policy*

Indonesia’s role was especially relevant to international pandemic preparedness efforts because the Indonesian variant of H5N1 appeared to be particularly virulent and hence of a particular risk to global health (see Elbe 2010: 479). Detailed knowledge of and further research and development based on this virus strain was therefore considered crucial for an effective health response. This informed the negative reactions by many states to the Indonesian decision not to share virus samples anymore:

“Many WHO Member States saw the Indonesian decision as undermining pandemic influenza surveillance and pandemic preparedness efforts, given that it impedes the WHO Network’s ability to monitor mutations in the H5N1 virus in Indonesia” (Molenaar 2010: 14; see also Hammond 2009)

In the view of its critics, Indonesia’s refusal to share H5N1 virus samples jeopardized international efforts to prevent a potentially devastating flu pandemic. This made Indonesia’s position unacceptable and unjustifiable from their perspective. Even before the 2007 decision to stop sharing viruses, Indonesia had been criticised for not sharing critical genetic data about the H5N1 outbreak at all, or not widely enough, and for thus hindering efforts to prevent a human H5N1 pandemic (see Sedyaningsih et al. 2008: 485; Hammond 2009). After the 2007 decision, the USA and the EU accused Jakarta of violating the 2005 revised International Health Regulations (IHR) which in their interpretation included an obligation to share virus samples along with information about possible pandemic risks (Hammond 2009; Fidler 2008: 91).<sup>14</sup> Northern countries emphasised cooperation in the WHO system to improve global health as an overarching goal, and underlined member states’ responsibility to support WHO efforts, including through providing virus samples (see Vezzani 2010: 2010). Moreover, they claimed that by jeopardising global health security with its refusal to share H5N1 virus samples, Indonesia acted against the objective of the IHR, an action which “could be considered [a] violation of its duty not to defeat the object and purpose of 2005 IHR before its entry into force [in 2007, UJ]” (Fidler 2008: 91). The refusal to share viruses with pandemic potential was thus seen as a violation of the spirit of the IHR, if not its letters (see Irwin 2010). Industrialised countries also questioned other legal arguments which Jakarta used to justify its position, namely the applicability of the CBD to pathogens as genetic resources (see Fidler 2008: 90–91; Vezzani 2010: 678–679). The relationship between the new pandemic influenza preparedness document and the CBD was intensely

14 The IHR, as revised in 2005, are binding on 196 countries who are parties to the agreement. The WHO plays a coordinating role in its implementation. The IHR contain provisions to build capacities in detecting and countering public health events, such as outbreaks of infectious diseases, and it obligates members to report on measures they have taken. They also represents a “framework for the coordination of the management of events that may constitute a public health emergency of international concern” <http://www.who.int/ihr/about/en/> (14.01.2014).

debated during the negotiations in Geneva (Molenaar 2011: 16; Molenaar 2011a: 5; Vezzani 2010: 678). Meanwhile, the interlinkage of both has been recognised in the WHO system (see e.g. WHO 2016, WHO 2019b). The WHO itself reportedly tried to maintain the impression that virus-sharing was an obligation of WHO members, or was at least tantamount to it (Hammond 2009; Irwin 2010; Krishnamurty/Herder 2013: 275; see Fidler 2008: 91).

Industrialised countries had fared well under the old GISN system, as they could exploit their privileged connections with and access to vaccine and anti-viral drug producers. Hence, they had no interest in promoting substantial changes to this system, especially not if those changes, as envisaged by Indonesia, would have resulted in a more equitable distribution of vaccines and drugs (see Elbe 2010: 483). Given the limited production capacities worldwide, this would very likely have meant a reduced supply available to them in the case of a flu pandemic. In the dispute about benefit-sharing and the distribution of vaccines and drugs, Indonesia's critics therefore wished to see intellectual property rights maintained to avoid hampering or discouraging future innovations, and not to risk under-supply of vaccine and drug stockpiles (Molenaar 2010: 15; Molenaar 2011: 15; Molenaar 2011a: 5; Vezzani 2010: 681). Indonesia's criticism was addressed to both industrialised countries and the big (Northern) pharmaceutical companies. In the state-centric WHO system, it then developed into a conflict mainly between Southern and Northern countries (see Vezzani 2010: 678, 681).

### 3.3 *Support for Indonesia's Policy*

Indonesia quickly won the support of a number of developing countries, including Brazil, India and Thailand (Elbe 2010: 479; Molenaar 2010a: 4), and, in May 2008, of the Non-Aligned Movement (Elbe 2010: 481). They shared Indonesia's perception of structural weaknesses and injustices in GISN which prevented developing countries' fair access to flu vaccines and antiviral drugs at reasonable cost, despite the crucial role of several of these countries in pandemic preparedness efforts (see Molenaar 2010a: 4; Sedyaningsih et al. 2008: 485, 487). They considered the existing system of vaccine development and distribution as "neither equitable nor transparent" (Irwin 2010).

Indonesia and its supporters argued that developing countries were disadvantaged in terms of economy and health preparedness anyway, and the inequitable distribution practices under GISN further aggravated this, especially in a situation of acute pandemic concerns. They drew on the principle of benefit-sharing in the use of genetic resources, which was under discussion at the time in the negotiations for the Nagoya Protocol (Irwin 2010). They interpreted this principle as also covering pathogens – a position that was contested at the time (see Fidler 2008: 90–91; Vezzani 2010: 678–679) – and wanted to connect virus-sharing directly with benefit-sharing, thus making the latter mandatory (Molenaar 2010a: 3). In their view, the inequitable access to vaccines diminished incentives for developing countries to participate in virus- and information-sharing, since they had to bear the high costs for vaccines and treatments themselves, whereas pharmaceutical companies gained profits from their cooperation (Irwin 2010). Through establishing the link with benefit-sharing, Indonesia and its supporters intended to secure the timely and affordable provision of public health care for their own populations in the case of flu outbreaks.

For developing countries, the imperative of benefit-sharing for the sake of more equitable global and national health care trumped the need to uphold intellectual property rights in the strict sense, especially as these rights had already been modified in favour of global health through the 2001 Doha Declaration. Hence, they wished to see intellectual property rights abrogated, or materials and products developed as a result of cooperation under

GISN exempted, or at least to see adequate compensation provided (Hammond 2009; Vezzani 2010: 680–683). Indonesia in particular emphasised its sovereignty over any resources collected on its territory, including pathogens (Fidler 2008: 90; Halabi 2019; Hameiri 2014; Vezzani 2010: 678). It rejected complaints that its refusal to share H5N1 samples represented a violation of the IHR, as in the Indonesian interpretation IHR obligations were limited to the sharing of relevant information, but not actual samples (see Fidler 2008: 92).

#### 4 THE NEW PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK

##### 4.1 *The Negotiation Process, 2007–2011*

Despite these numerous conflicting normative and legal claims, no party to this dispute questioned the principle of international cooperation to promote global health. What was questioned, however, was the legitimacy of the *existing* system of pandemic influenza preparedness. The conflict was articulated mainly within the WHO, through the work of inter-governmental meetings convened by the Director-General and through the World Health Assembly (WHA) (WHO n.d). In Indonesia's view, the negotiation process should result in a more equitable system of benefit-sharing in influenza preparedness. From the industrialised countries' perspective, it should ensure that an effective network of pandemic influenza preparedness would be maintained that would not compromise their national health and commercial interests. As WHO member, Indonesia remained formally included in the proceedings as negotiation partner on an equal footing despite its withdrawal from GISN. Early on in the process, which comprised a series of meetings of varying groups of actors, Indonesia tabled concrete proposals as to how the WHO flu virus-sharing system could be re-structured to make it more equitable (Hammond 2009). At the same time, WHO officials and member states' representatives tried to work out compromises that would reconcile the Indonesian call for institutionalised benefit-sharing and industrialised countries' (and WHO's) interest in uninhibited access to flu virus samples (Irwin 2010) and would induce Indonesia to resume sharing of H5N1 samples (Fidler/Gostin 2008: 171). These included offers to provide vaccine supplies (Elbe 2010: 482). However,

“rather than simply accepting those offers of material support, and resolving the dispute there and then, the Indonesian health minister instead formulated a much stronger demand that made Indonesia's resumption of virus sharing conditional upon a more fundamental reformation of the whole virus-sharing mechanism” (Elbe 2010: 482; see also Sedyaningsih et al. 2008: 486–487).

Indeed, apart from a few samples sent to WHO laboratories in the course of 2007 and the release of genetic information, Indonesia remained reluctant to resume full cooperation in the form of virus-sharing at least until 2009 (Irwin 2010).

Any potential discursive dominance of Northern states in the WHO forums was countered by the sheer number of supporters Indonesia could garner among developing countries (see e.g. Hammond 2009). Moreover, Indonesia's repeated refusal to share viruses exerted strong pressure on industrialised countries to at least participate in the negotiation process, since these countries had a great interest in the continuation of virus-sharing (see Elbe 2010: 477): Their governments found themselves under domestic public pressure to ensure preparedness for a potential pandemic – and preparedness, including sufficient vaccine stockpiles, depended on virus-sharing.

The conflict gained additional urgency with the 2009 human swine flu (H1N1) pandemic, which occurred rather unexpectedly and demonstrated the need for effective pandemic

influenza preparedness.<sup>15</sup> This outbreak also confirmed Indonesia's and developing countries' concerns about the inequitable nature of the current system, as developed countries stocked nearly all available vaccine doses, while – even after WHO and UN intervention and subsequent vaccine donations – developing countries were left with inadequate means to protect their populations against H1N1 (Fidler 2010: 1). This experience supported developing countries' complaints about the inequitable and unjust nature of the current system (Fidler 2010: 2). However, it did not change the positions of other actors, in particular industrialized countries (Fidler 2010: 2); if anything, it cemented existing conflict lines as it proved to industrialized countries how they would have something to lose in a system that denied them preferential treatment, for instance by way of advance orders on vaccines (Fidler 2010: 2–3).

Indonesia pursued its objectives through a mixture of more radical and more conventional strategies. Following the unprecedented and unparalleled withdrawal from GISN, it opted for a traditional negotiation process in the course of which it used its H5N1 samples as bargaining chips to further its objectives (Elbe 2010: 482).<sup>16</sup> Since Indonesia itself was interested in pandemic influenza preparedness cooperation, it did not aim to abolish any international cooperation, but rather tried to use its leverage to add a strong benefit-sharing dimension to existing practices (see Vezzani 2010). With its emphasis on structural inequalities and cross-references to related debates in other international forums, in particular the CBD, it gained the support of a large number of developing countries. The exploitation of genetic resources while access to pharmaceutical products was unevenly distributed, in combination with the inequitable public health care available in North and South (Stevenson/Cooper 2009: 1387), apparently worked as strong mobilising arguments. Developing countries seem to have accepted the Indonesian strategy as legitimate, even though no other country followed its example to cease cooperation under GISN (Fidler 2010: 2).

While Indonesia's critics framed its actions as illegitimate, apparently they could not fully delegitimize Jakarta's claim for a more equitable system of benefit-sharing. This is indicated by the fact that talks and negotiations did not only commence within a few months after Indonesia's withdrawal from GISN, but were also maintained despite difficult and tense discussions and were ultimately brought to a consensual compromise conclusion in May 2011.

#### 4.2 *The PIP Framework: A New Norm of Sharing Viruses and Benefits?*

At the end of the 4-year negotiation process, WHO members agreed on a new *Pandemic Influenza Preparedness Framework* (PIP Framework).<sup>17</sup>

“This Framework is an international agreement that brings together stakeholders from WHO Member States, industry and civil society with the goals of ensuring the sharing of influenza viruses with human pandemic potential through a WHO coordinated network of public health laboratories, and the promotion of fair and equitable access to benefits, such as vaccines and antiviral drugs that arise from that sharing” (Gellin/Ampofo 2014).

It includes innovations that largely correspond to Indonesia's demands such as a more equitable distribution of access to vaccines and drugs. Moreover, it was agreed that producers of vaccines, diagnostic equipment and drugs should make a financial contribution

<sup>15</sup> Luckily, the H1N1 virus, though easily transmitted from humans to humans, did not cause as many casualties as some may have feared initially.

<sup>16</sup> For a detailed account of Indonesia's actions during the negotiations see Irwin 2010.

<sup>17</sup> For WHO information on the PIP Framework see <https://www.who.int/influenza/pip/en/> (16.02.2020).



(“Partnership Contribution”) which shall cover 50% of GISN’s running costs and be used for the enhancement of pandemic preparedness (WHO n.d.: 2).

There are now two Standardised Material Transfer Agreements (SMTAs) that serve as basis for flu virus-sharing activities (see Krishnamurthy/Herder 2013: 280–283). The inclusion of such SMTAs in the new framework was heavily disputed (Vezzani 2010: 681), with developing countries being strong proponents and the US being opposed (Irwin 2010). The outcome reflects the different positions on patent protection. The first SMTA relates to cooperation within GISRS. Neither the originating countries of virus samples nor laboratories cooperating in GISRS will “obtain any intellectual property rights (IPRs) on the Materials [virus samples, UJ]” (Molenaar 2011a: 5). As for the second SMTA, vaccine and drug manufacturers outside GISRS can choose between several benefit-sharing options through which they make their products accessible to everyone: They can donate 10% of current vaccine stockpiles to the WHO, or sell them at reasonable prices; they can issue royalty-free licences to producers in developing countries, or they can provide royalty-free non-exclusive licences on IPR to the WHO (Molenaar 2011a: 5).

The PIP Framework represented a compromise in which all parties made significant concessions (for the developing countries see Krishnamurthy/Herder 2013). Most countries involved in the negotiations welcomed the agreement on the PIP Framework. “The Indonesian delegate further noted that this global system is more equal and more transparent and that the Framework will contribute to increased preparedness” (Molenaar 2011a: 6). At least on paper there are significant changes compared to the old system of cooperation: The decades-old cooperation principle was reinforced, and in addition to that, benefit-sharing was indeed established as a principle on an equal basis with that of virus-sharing. The protection of intellectual property rights was not abandoned, but modifications and compensation were included in the agreement. One significant innovation was the fact that industry representatives openly acknowledged their responsibility to collaborate with WHO (Molenaar 2011a: 5).

However, the PIP Framework is not a legally binding document and does not contain any enforcement provisions. To be implemented successfully, it depends on the cooperation of pharmaceutical companies and vaccine producers. Developed countries are under no obligation to contribute to a more equitable distribution of vaccines (Fidler/Gostin 2011: 201).

“Instead, the PIPF [PIP Framework, UJ] allows developed countries to shift the onus to manufacturers, calling on member states to ‘urge’ manufacturers to donate pandemic and interpandemic vaccines, to make them more accessible to developing countries through tiered pricing and to engage in technology transfer” (Krishnamurthy/Herder 2013: 281).

The implementation process started off difficult and slow (see Kamradt-Scott 2012: 4; Kamradt-Scott 2013), but the PIP Framework now seems to be working relatively effectively (for a WHO perspective see Huvos/Khan 2016). For instance, as a WHO study reported in 2018, “all current major influenza vaccine manufacturers have signed SMTA 2s with WHO” (WHO 2018: 18). Experts have commented positively on the Framework but have also pointed to remaining shortcomings, e.g. uncertainty regarding its ability to ensure benefit-sharing in case of an influenza pandemic (see Kamradt-Scott/Lee 2011: 839; Rourke 2019). Moreover, new conflicts arose with regard to virus-sharing and the protection of genetic resources.



## 5 NORM CONFLICTS AND LINKAGES IN THE CONTEXT OF VIRUS- AND BENEFIT-SHARING<sup>18</sup>

As the previous sections demonstrated, pandemic influenza preparedness does not exist in isolation from other policy fields, even though cooperation in issues related to world health and global health governance is first and foremost based on the WHO Constitution. The Constitution postulates that the “enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being” (WHO 2020: 1). The right to health is thus a human right (UNHCR/WHO 2008) and was later established as part of the human security agenda (see Chen/Narasimhan 2003; Irwin 2010). Cooperation in GISAID to advance influenza preparedness had been embedded in this broader normative framework and for decades functioned reasonably well, with the expectation that virus strains should be shared freely for the benefit of all and in order to improve global health. It is disputed among experts to what extent cooperation and virus-sharing represented *legal* obligations (Vezzani 2010: 677), though the arguments denying such a legal obligation seem more forceful (see Fidler 2008: 90). It seems clear, however, that there was a *moral* expectation of states to abide by its principle.<sup>19</sup> This principle was reinforced by the WHO’s revised International Health Regulations which are binding on all WHO members and which explicitly include an obligation for members to cooperate if serious public health events arise (WHO 2008: 12 (IHR Art. 6 and 7)). There was and remains thus a solid normative basis for the expectation that viruses, and other pathogens, for that matter, should be shared for the sake of global health.

However, over the past decades a new norm has evolved that stands in potential conflict with this expectation: access and benefit-sharing, i.e. the principle that benefits arising from the utilization of genetic resources of one country should be shared equitably between the origin country and the beneficiary. The claim to benefit-sharing did not only pose challenges for international health cooperation (see below). It also brought its proponents, mostly located in the Global South, into conflict with industrialised countries over intellectual property rights as granted by the TRIPS Agreement. In the case of pandemic influenza preparedness, the dispute about the sharing of benefits and the protection of intellectual property rights concerned mainly antiviral drugs and flu vaccines. However, this is but one manifestation of the more general dispute between developing and developed countries about the exploitation of resources without adequate sharing of the benefits thus gained. In fact, the TRIPS Agreement had been challenged in the health realm before: The 2001 Doha Declaration specified that TRIPS “does not and should not prevent members from taking measures to protect public health”<sup>20</sup>, and

“[f]or the purposes of public health protection, the Doha Declaration accepted that the human right to essential medicines also formed a legitimate part of the world trade order. The promotion of public health was adopted as guiding precept in the interpretation and implementation of TRIPS. Most notably, restriction of the production of compulsorily licensed medicines to the domestic market was relaxed (Wolf/Scholz 2017: 60).

Intellectual property rights, as far as they apply to pharmaceutical and other health-related processes and products, have thus been modified for the benefit of global public health; the human right to health took precedence over intellectual property rights (see Wolf/Scholz 2017). The claims Indonesia and its supporters made in the pandemic influ-

<sup>18</sup> For a theoretical approach to norm linkages see e.g. Fehl 2018.

<sup>19</sup> David Fidler argues that the Indonesian sovereignty claim over H5N1 viruses isolated in its territory “cut against the ethos and practice of sample sharing under which GISAID had operated” (Fidler 2008: 90).

<sup>20</sup> [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (14.01.2014).

enza case were probably informed by these developments. They provided a broader context for the demand that benefit-sharing should be a mandatory component of any future virus-sharing regime. At the same time, some experts have voiced strong concerns that the access and benefit-sharing norm may have negative implications for global health preparedness (see e.g. Ribeiro et al. 2018).

The notion of benefit-sharing was already present in the 1993 Convention on Biodiversity (CBD) which contains as one of three core principles the “fair and equitable sharing of benefits arising out of the utilization of genetic resources”.<sup>21</sup> This principle has been elaborated and operationalized inter alia in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. The Nagoya Protocol was concluded in 2010 after almost one decade of negotiations and entered into force in October 2014.<sup>22</sup> It balances “appropriate access to genetic resources and [...] appropriate transfer of relevant technologies” with the “rights over those resources and to technologies”<sup>23</sup>, thus trying to reconcile claims to the sharing of genetic resources for the benefit of all, the widest possible access to relevant technologies, and the protection of (intellectual) property rights and genetic resources. To implement its provisions, states parties are required to enact national “legislative, administrative or policy measures on accessing sovereign genetic resources, as they choose” (Rourke et al. 2019: 7). This leaves members a certain leeway in interpreting the Protocol (see Ribeiro et al. 2018: 404). The CBD also stipulates that utilization of one country’s genetic resources requires prior consent of and, if practicable, continuing cooperation with the country of origin (CBD Article 15).

The question whether or not pathogens are covered by the CBD’s and the Nagoya Protocol’s definition of ‘genetic resources’ was contested among states and scholars when the PIP Framework was negotiated (see Fidler 2008: 90–91; Irwin 2010; UNCTAD 2014; Vezvani 2010: 678–679). By now, the interpretation that pathogens are ‘genetic resources’ in the Nagoya Protocol’s sense seems to have prevailed in discourse and in practice (see Cressey 2017; Nelson 2019; Srinivas 2017; Third World Network 2019). This does not mean that the norm conflict is resolved, however. To the contrary: If pathogens count as genetic resources to be protected by the Nagoya Protocol, their transfer requires prior individual agreements between origin and recipient state by default as stipulated by the Protocol. This may create challenges for international health cooperation and emergency response, which often depend on rapid and wide sharing of samples; it also complicates the scientific research processes more generally (see e.g. Cressey 2017; Nelson 2019; Ribeiro et al. 2018; Smith et al. 2017).<sup>24</sup> The negotiators of the Protocol took this into account when they included “the importance of ensuring access to human pathogens for public health preparedness and response purposes” in its preamble, and in Article 8 (b) obligated states parties to

“[p]ay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the

21 <http://www.cbd.int/intro/default.shtml> (17.12.2013).

22 Kanth 2013: 15; <https://www.cbd.int/abs/> (04.12.2019).

23 Nagoya Protocol, Article 1, <http://www.cbd.int/abs/text/articles/default.shtml?sec=abs-01> (14.01.2014).

24 For example, the annual process to develop an effective vaccine against the seasonal flu depends on the rapid sharing of information about the circulating strains to allow for the production of a matching vaccine in time for the next flu season. Experts fear that this process might be disrupted if individual agreements have to be negotiated under the Nagoya Protocol for these viruses (see Cressey 2017).

use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.”

Moreover, Article 4(4) includes a provision that exempts “specialized international access and benefit-sharing instrument[s]” from the Nagoya Protocol’s requirements. The PIP Framework could arguably represent such an instrument (see Saez 2017; Srinivas 2017). However, despite these concessions, there remains a tension between the protection of genetic resources and the sharing of pathogens and samples for global health purposes.

In 2016, the WHO Secretariat published a study that analyses the implications of the Nagoya Protocol for public health (WHO 2016). This study concluded that the Nagoya Protocol’s provisions may have negative effects on the speed and extent of pathogen-sharing. However, if implemented comprehensively, it may also foster global health cooperation since it provided a stable framework of expectations and incentives regarding pathogen- and benefit-sharing practices (WHO 2016). A second report submitted in 2019 remains vague in its assessment of the actual practical implications but emphasises the need for national implementation that allows and facilitates the timely sharing of pathogens for the sake of global health (WHO 2019a).<sup>25</sup> The WHO regularly consults with the CBD Secretariat on this issue<sup>26</sup>, and in May 2019 the World Health Assembly (WHA) requested the Director-General to “provide information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications” and to provide another report to the WHA in 2021.<sup>27</sup> The norm conflict, while as yet unresolved, is thus openly acknowledged and reflected in the every-day business of the WHO.

## 6 CONCLUSION

By ceasing cooperation in the established framework of virus-sharing, by forcing other states to re-negotiate that framework, and by adding benefit-sharing as integral part to this normative system, Indonesia initiated a substantial reorganisation of the existing system of pandemic influenza preparedness – a policy field that is very specific yet of major global public health concern. Indonesia’s success was a function of different variables. The facts that there were major concerns at the time that an influenza pandemic might be imminent and that the virus strain circulating in Indonesia was considered key in the efforts to prevent this pandemic provided a window of opportunity and gave Indonesia disproportionate leverage in the process. Moreover, by invoking long-standing grievances over the exploitation of the Global South by the Global North in public health and other realms, Indonesia could garner broad support for its stance among developing countries. Finally, through tying its vision for a reformed virus- and benefit-sharing system to the broader emerging norm complex of benefit-sharing and the protection of genetic resources, Indonesia anchored its claims in a wider normative context.

The normative shift entailed in the renegotiation process for the PIP Framework is not limited to pandemic influenza preparedness: The intertwining of global health, access and benefit-sharing, and the protection of genetic resources is now manifest in global health

25 For a critical view of the WHO assessment see e.g. GISAID 2019. For a more negative assessment of the implications of the Nagoya protocol on global health and research see e.g. Knauf et al. 2019.

26 <https://www.who.int/departments/science-division/public-health-implications-of-implementation-of-the-nagoya-protocol> (12.12.2019).

27 See WHA 72(13), 28 May, 2019, [http://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\(13\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(13)-en.pdf) (12.12.2019).

politics on a larger scale (see WHO 2016; WHO 2019b). Recent debates in the World Health Assembly illustrate this: Reportedly “developed countries mainly focused on the impact of the Nagoya Protocol on pathogen sharing, especially expressing concerns over delay in sharing samples” (Third World Network 2019). At the same time, “developing countries strongly supported the objectives and principles of the CBD and the Nagoya protocol, seeing the latter as an opportunity for equity globally, through fair and equitable benefit sharing which in turn will reinforce public health preparedness and response during an emergency” (Third World Network 2019).

This norm conflict is exacerbated by technological developments, particularly in genetic engineering. Due to major technological advances, genetic sequencing nowadays plays a much bigger role in the surveillance, detection and diagnosis of infectious diseases as well as in research into remedies and countermeasures. Often a gene sequence rather than the whole pathogen is used in the research nowadays. Genetic sequence data thus assume a similar role as pathogen samples used to play, raising the same problem: If genetic sequence data are shared without regulation, and if benefits are gained from these sequences in countries other than the country of origin, the international community would be back at square one in terms of balancing the sharing of viruses (i.e. their genetic sequences) and benefits. Consequently, in a review of the PIP Framework in 2016 the Review Group included in its recommendations the proposal that genetic sequences should be treated like actual virus samples under the PIP Framework; this has not (yet) been implemented, however (Saez 2017; WHO 2016a; WHO 2018). Likewise, the question to what extent genetic sequences are or should be covered by the Nagoya Protocol is still subject to debate (Branswell 2019; Nelson 2019; Rourke et al. 2019: 9–10; Ribeiro et al. 2018: 404; WHO 2018 20–22). Genetic sequencing thus adds yet another contested layer to the norm complex. A theoretical analysis of this complex, its evolution and its current dynamics is beyond the scope of this paper but would merit future research – as would the consideration how these norm conflicts and contestations play out in global health more generally and in other policy fields.<sup>28</sup>

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<sup>28</sup> See for instance Rourke et al. (2019) for a study on how the Nagoya Protocol might impact on UN investigations of alleged biological and chemical weapons attacks.

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