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**Developing Countries, Vaccine Access and Influenza
Outbreaks: Ethics and Global Health Governance When Facing
a Pandemic**

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The threat posed by influenza pandemics raises serious ethical issues, as well as questions of global health governance. In order to create pre-pandemic vaccines, global health authorities need access to virus from regional outbreaks. But because the countries where these outbreaks occur are unlikely to benefit from the vaccine, they are sometimes reluctant to share this seed stock, and may try to make proprietary arrangements with pharmaceutical companies, as briefly occurred in Indonesia. Although these arrangements may increase developing countries' access to vaccine, they hamper the global cooperation necessary to prepare for influenza outbreaks. Developing countries, in contrast, point to the United States' decision not to use adjuvants in influenza vaccines with the 2009 H1N1 outbreak, even though this is common in Europe, and it might make tens of millions of individual doses available for donation to developing countries. Similar issues bedevil preparation efforts, particularly concerning advance contracts for vaccines. This paper will examine a number of these challenges, and the global health policies needed to address them, based on Indonesia's 2007 decision not to share viral samples with the WHO, as well as events during the 2009 H1N1 pandemic.

Influenza

Developing countries have long pointed to aspects of the World Trade Organization (in particular the Trade Related Aspects of

Intellectual Property agreement), which they feel unfairly hamper efforts to fight major epidemics. During the 1990s these disputes led to a major struggle around providing generic drugs to people living with HIV. This contest pitted the United States and pharmaceutical companies, on the one hand, against developing countries and non-governmental organizations, on the other. While this contest ended with a victory for the Global South, more recently, issues of global health equity have focused on influenza.

The influenza virus is a very contagious agent that causes a respiratory disease. In the Northern hemisphere the flu season usually begins in October and peaks around February. The opposite is true in the Southern Hemisphere. For most people flu causes the rapid onset of exhaustion, aches, headache, coughing and heaviness in their chest. In most cases, with some time in bed and a little care, the flu quickly passes. But flu is a highly mutagenic virus, which sometimes undergoes major changes, in particular when a form adapted to birds enters into humans or other animals. In this case, the world can see a devastating pandemic.

The worst pandemic of the twentieth century struck in 1918, when an avian form of the flu adapted to humans, and began to spread rapidly, perhaps from Haskell County, Kansas. By the time that the disease had run its course perhaps 40 million people had died, from the hills of Northern India, the country most devastated by the disease,

to the trenches of Western Europe during World War One.¹ Many famous people, such as Woodrow Wilson, may have been infected by the disease, which also killed William Osler, the outstanding physician of the age.² As Alfred Crosby and Arno Karlen have argued, one of the most unusual aspects of the pandemic is that it has been largely forgotten.³

Significant influenza pandemics also swept the globe in 1957 and 1968, although neither caused the mortality of the 1918 outbreak. In some respects, little has changed in the intervening decades. We do have some treatments now for the flu. There are currently four drugs used to treat influenza, which can only be obtained in most developing countries with a prescription. All must be taken within a short period of developing symptoms, and none cures the illness. Instead, they shorten the course of the disease and alleviate suffering. Vaccines are also available, but they currently represent an imperfect means to address this threat. The flu virus mutates rapidly and there are many different strains, each characterized by different proteins in their outer

¹ Mike Davis. *The monster at our door: The global threat of avian flu*. (New York: The New Press, 2005), 26, 32.

² Barry, J.M. *The great influenza: The epic story of the deadliest plague in history*. (New York: Penguin, 2005), 387.

³ Alfred Crosby, *America's forgotten pandemic: The influenza of 1918*. (New York: Cambridge University Press, 1990); Arno Karlen. *Plague's progress: A social history of man and disease*. (London: Victor Gollancz. 1995), 145.

shell. Every year scientists scour the planet looking for different forms of the virus. They then have to guess which forms will likely dominate epidemics in the coming winter (for each hemisphere). They come to a consensus on three different forms. It then takes months to grow the virus in chicken eggs. One challenge is that vaccine designers sometimes guess incorrectly, and a strain of virus will circulate widely which is not covered by that year's vaccine. Another risk is that a novel form will appear for which the vaccine developers are completely unprepared.

The current vaccine technology has other limitations, not the least of which is that entails the use of millions of chicken eggs, which are not only time consuming, but also could be difficult to obtain if a bird flu pandemic wiped out chicken farms. Contamination can also be a challenge, as proved the case in October 2004, when a plant owned by Chiron in the United Kingdom produced a vaccine contaminated by a bacteria. This one failure meant that the U.S. health system lost tens of millions of expected doses of vaccine.⁴ The U.S. media asked how the country could deal with pandemic flu, if it could not guarantee a vaccine supply in a normal year? For this reason, as well as to shorten the time entailed for vaccine preparation, there is currently a major effort to create new vaccine technologies, which would no longer rely on old egg-based approaches to production. Recent events have made

⁴ Davis, 140-144.

this a high priority for the United States government, as well as other global health actors.

Initially, global health officials focused on the threat from bird flu. In 1997, an outbreak of bird flu in Hong Kong sickened eighteen people and killed six. The government killed more than a million chickens in a few days, which stamped out the outbreak.⁵ But this was not the only appearance of bird flu. In February 2004, an outbreak of a different strain of bird flu in the Fraser Valley of British Columbia caused the Canadian Food Inspection Agency to order the destruction of nearly twenty million chickens. In 2003 and 2004 bird flu again appeared in South East Asia, particularly in Vietnam, and it has since spread to countries as geographically distant as Turkey and Indonesia. Then in 2009 a new form of influenza, novel H1N1 (the so-called swine flu) emerged in Mexico. In the end, the 2009 pandemic did not resemble that of 1918. This was fortunate because in the northern hemisphere most people did not have access to the vaccine until after the epidemic had peaked.

Even before the 2009 pandemic, efforts to fight the flu raised key moral questions. European and North American governments collectively spent billions of dollars stockpiling medications, testing vaccines, and encouraging basic research on the flu. At the same time, developing nations struggling to contain bird flu found comparatively

⁵ Davis, 45-54.

little aid forthcoming for tasks such as culling infected flocks. With the emergence of H1N1, developed countries were able to activate pre-existing contracts with major vaccine manufacturers, which gave their countries first access to the vaccines produced. The manufacturers would not take orders from poorer but more populous countries, because they did not have the capacity. This inequality threatened international efforts to contain flu pandemics.

Indonesia

Even before the emergence of novel H1N1, developing nations proved reluctant to collaborate with First World nations to develop possible vaccines, because they knew they were unlikely to benefit from this research in the event of an outbreak. In some cases, developing countries may have sought access to vaccines in the event of an outbreak, by making deals with companies that could provide vaccine in exchange for access to emerging viral strains. Indonesia, for example, did not want to share strains of the bird flu collected from fatalities because the country unless it was guaranteed access to any vaccine developed from this resource:

In January, frustrated that an Indonesian strain of the virus had been used to make a vaccine that most Indonesians would not be able to afford, the country stopped cooperating with the W.H.O. and made a deal to send

samples to Baxter Healthcare, an American company, in return for a low-cost vaccine and help in building vaccine factories in Indonesia. Some other poor countries applauded the move and debated whether to follow suit, a move that could have set back global vaccine research. Yesterday, Indonesia's health minister, Siti Fadilah Supari, told reporters in Jakarta that she would resume sending samples to the W.H.O. "immediately."⁶

In return, the W.H.O. agreed that it would not share its samples with vaccine manufacturers. This deal, however, failed to end the conflict.

Supari soon returned to make even more serious accusations against the United States, which shocked many observers: "Indonesian health minister Siti Fadilah Supari, who is at the center of an international controversy over (the) sharing of H5N1 avian influenza samples, recently claimed that developed countries are creating new viruses as a means of building new markets for vaccines, according to an Agence France-Presse (AFP) report. In February, Supari published a 182 page book titled *Time for the World to Change: God is Behind the Avian Influenza Virus*, which alleges that the United States intended to produce a biological weapon with the H5N1 virus and the World Health

⁶ McNeil Jr., D.G. (March 28, 2007). "Indonesia to send bird flu samples, with restrictions." *New York Times*. Accessed online at http://www.nytimes.com/2007/03/28/world/asia/28birdflu.html?_r1&oref=slogin@page2...; see also Elbe, 481.

Organization (WHO) was conspiring to profit from H5N1 vaccines.”⁷ Supari may have been surprised by the attention the book attracted, as “the English translation of the book was officially withdrawn by her (due to what she claims were inaccuracies in translation).⁸ Indonesia also threatened to close a key U.S. Navy Medical Research Unit that engaged in surveillance of avian influenza, because it feared the facility sought to weaponize bird flu.⁹ Stefan Elbe has suggested, however, that her real concern may have been that this facility would share viral samples with U.S. government agencies, which would undermine Indonesia’s bargaining position both with the WHO and with the developed world.¹⁰

As part of her argument, Supari had made arguments regarding “viral sovereignty.” In this approach, viruses formed part of the biological patrimony of the nations in which they were found, which held exclusive rights to them. This idea attracted support amongst developing countries, such as India, which viewed this approach as a means to strengthen their bargaining position with the pharmaceutical companies that provided vaccines. The Indonesian government itself

⁷ Schnirrer, L. (2008, September 8). Supari accuses rich nations of creating viruses for profit. *CIDRAP News*, search the archive at www.umn.edu.

⁸ Elbe, 480.

⁹ Holbrooke, R. and L. Garrett. (2008), August 10. “‘Sovereignty’ that risks global health,” *Washington Post*, accessed online at www.cfr.org/publication/16927. She continued to make this argument in 2009. See Stefan Elbe, “Haggling over Viruses: the Downside Risks of Securitized Infectious Disease,” *Health Policy and Planning*, (2010) 25, p. 477.

¹⁰ Elbe, 482.

was divided over this argument, but it attracted a powerful response in the West.¹¹ Laurie Garrett and Richard Holbroke published an article in the *Washington Post*, to denounce this concept, which they argued would undermine the kind of global cooperation required to face the next influenza pandemic. The authors called on China to use its influence with Indonesia, and for the United States to exercise muscular diplomacy. The issue was particularly important because in 2007 Indonesia had reported the largest number of H5N1 cases in the world, with a case fatality rate of 81%.¹² Moreover, in 2007 it appeared that the mortality rate from avian flu in influenza in Indonesia was steadily increasing “from sixty-three percent in 2005 to eighty percent in 2006 and nearly eighty-seven percent in 2007.” These figures, and the fear that they created, did much to shape the ensuing debate.¹³

Supari’s conspiracy theories are nothing new to people who study HIV. Similar stories appeared in Haiti in the 1980s, as people accused the U.S. government of creating the virus to eliminate the islands’ population. But it would be a mistake to associate Indonesia’s concerns solely with these statements by the former minister of health. Indeed, Indonesia’s President stated that in “Indonesia, we recognize that there are issues to be resolved in the world health system, but

¹¹ Elbe, 477.

¹² Endang R. Seyaningsih, Siti Isfandari, Trioni Soendoro and Siti Fadilah Supari, “Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Case of Influenza.” *Annals Academy of Medicine Singapore*. 2008; 37: 482-8.

¹³ Kenan Mullis, “Playing Chicken with Bird Flu: ‘Viral Sovereignty,’ the Right to Exploit Natural Genetic Resources, and the Potential Human Rights Ramifications,” *American University International Law Review*, 24:943 (2009), 947-948.

certainly we don't believe in conspiracy theories."¹⁴ While Supari's statements were outrageous, a broader set of concerns were neither confined to Indonesia, nor mainly based on "conspiracy theories." Instead, they reflected the diverging interests of developed and developing countries as they faced a potential pandemic. Indonesian authors pointed out that the International Health Regulations, which were revised in 2005, did not specifically state that nations had to share biological samples.¹⁵ They complained that the results of studies of these samples were being shared without information first being provided to Indonesia. But they were most concerned that pharmaceutical companies were developing vaccines using their seed stocks without their permission, which finally provoked their decision to stop cooperating with the WHO:

Toward the end of 2006, a call by a journalist to the Indonesian MOH confirming news that an Australian vaccine company's plan to develop vaccine against H5N1 virus strain that Indonesia had provided to the WHO system triggered Indonesia's drastic action. The fact that pharmaceutical companies had access to Indonesian (vaccine seed) viruses that were shared with the WHO affiliated laboratories was not only in violation (again) of

¹⁴ Lisa Schnirring, "Supari accuses rich nations of creating viruses for profit," CIDRAP, September 8, 2008, accessed on-line at www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/sep0808indonisa.ia-br.htm.

¹⁵ Seyaningsih, et al., 484.

the WHO guidance for virus sharing (March 2005), but also –as strongly argued by Indonesia- revealed the unfairness and inequities of the global system.¹⁶

The WHO recognized that this was a major issue, which extended beyond the perceptions of one government official. The WHO sent representatives to Indonesia in February, which had agreed in March to resume sharing samples on a provisional basis, and by May of 2007 a working group was formed to begin studying this problem.¹⁷ But these steps failed to resolve the dispute.

Despite the anger that Indonesia's position created in developed countries, the country could continue to count on international support. In February 2007 the medical journal *the Lancet* published an editorial in response to Indonesia's declaration, which said that the WHO needed to achieve an agreement that would demonstrate solidarity in preparing for the next pandemic.¹⁸ Non-aligned nations also found Indonesia's argument to be attractive. In May of 2007 Indonesia raised these questions at a meeting of the World Health Assembly. During this meeting, developing countries launched a critique of how the World Health Organization had shared viral seed stock samples:

In the course of these deliberations, it emerged that WHO

¹⁶ Sedyaningsih, et al., 486.

¹⁷ Sedyaningsih, et al. 487.

¹⁸ For discussion of this issue see Chan Chee Khoo, "Equitable Access to Pandemic Flu Vaccines," a paper presented at the *Conference on Strengthening Health and Non-health Response Systems in Asia*, March 18-19, 2010, Singapore. Accessed on-line from Third World Network" on January 28, 2011 at www.twinside.org.sg/title2/health.info/2010.health20100303htm.

had not abided by the terms of the 2005 WHO guidelines on sharing of viruses which required the consent of donor countries before WHO's collaborating centers could pass on the viruses (other than the vaccine strains) to third parties such as vaccine manufacturers. While discouraging the use of material transfer agreements (MTAs) at the point when donor countries transferred their virus samples to the WHO, WHO's collaborating centers nonetheless resorted to MTAs when they transferred to third parties vaccine strains containing parts of the viruses supplied by developing countries such as Indonesia, Vietnam and China. Indeed WHO's collaborating centers themselves, as well as third parties, had sought patents covering parts of the source viruses used in developing vaccines and diagnostics.¹⁹

Perhaps because of these revelations, twenty developing countries entered a resolution to the World Health Assembly "calling for a new international framework to be set up for the sharing of avian influenza viruses, to review the existing WHO research system and to prioritize the manufacture and availability of vaccines in developing countries."²⁰

The goal of this resolution was to provide rights to those

¹⁹ Chan Chee Khoo, p.2.

²⁰ Martin Khor, "Developing Countries Call for New Flu Virus Sharing System," *South-North Development Monitor (SUNS) #6253*, May 15, 2007. Accessed on February 2, 2011 at www.twinside.org.sg/title2/avianflu/news.stories/afns.006.htm

countries that shared viral seed stock samples. From the perspective of developing countries, they saw little benefit from sharing viral samples with the World Health Organization. They perceived that these samples were being shared improperly with companies that used them to create vaccines for profit, which were then sold at prices far too high for the developing world to purchase. For this reason, the resolution stated that any “vaccines, diagnostics, anti-virals and other medical supplies arising from the use of the virus and parts thereof must be made available at an affordable price and in a timely manner to the developing countries, particularly to those under the most serious threat or already experiencing the pandemic threat.”²¹ This resolution was opposed by the United States, which was particularly concerned that changes to the “Material Transfer Agreements” (which governed viral seed stock sharing) might undermine global collaboration to produce vaccines against pandemic strains of the vaccine. In the end, the World Health Assembly passed a resolution calling on the WHO to create a vaccine stockpile, as well as “new terms of reference for the sharing of influenza viruses.”²² Nonetheless, the WHA resolutions failed to create a comprehensive framework to address these issues. Even so, Indonesia has returned to sharing viral samples with the WHO, as part of the Global Influenza Surveillance Network (GISN).²³

²¹ Khor, p.3.

²² Chan Che Khoon.

²³ For an excellent overview of this history see Rachel Irwin, “Indonesia, H5N1, and Global Health Diplomacy,” *Global Health Governance*, 3:2, Spring 2010, accessed online on January 2, 2011 at www.ghgj.org.

While developing nations –such as India, Thailand and Brazil- sympathized with this position, there have been substantial critiques of Indonesia’s position, both by developed states and international law experts.²⁴ One challenge for Indonesia is that viruses do not respect borders. Because of this reality, how can they be considered an aspect of biodiversity under the Convention on Biological Diversity (CBD)?²⁵ The Indonesian precedent also seemed to threaten health in other nations, which was prohibited by article three of the CBD.²⁶ In other words, the very convention that Indonesia was invoking to uphold its position, appeared to prohibit Indonesia’s decision to withhold viral seed stocks. Similarly, Kenan Mullis has argued not only that Indonesia’s position likely violated article twelve of the International Convention on Economic, Social and Cultural Rights, but also that the means for its protest are too severe to be justified given the end that it seeks to achieve.²⁷ In sum, although Indonesia’s position attracted much sympathy because it evoked the frustrations of many developing countries, it stood on shaky legal ground.

As more information became available, it also became clear that Indonesia’s position, at least initially, may have been focused on more than bird flu alone. Indeed, it seemed that the WHO had managed to address many of Supari’s immediate concerns in 2007:

²⁴ For the nations supporting Indonesia’s position, see Elbe, 479.

²⁵ Mullis, 955.

²⁶ Mullis, 957.

²⁷ Mullis, 958, 967

. . .Supari also felt sufficiently emboldened to hold out for more than just a few concessions made by the West, and to push for a fundamental transformation of the virus-sharing mechanism. When, for example, she was approached by the WHO with offers of a laboratory upgrade and as much vaccine as they needed in February 2007, she turned these offers down. . . Rather than simply accepting these 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.²⁸

From this perspective, the WHO appears to have made reasonable accommodations to the concerns of Indonesia, but was rebuffed.

The 2009 Novel H1N1 Pandemic.

Despite numerous discussions in various forums, the global health community had made little progress on this issue by the time of the 2009 pandemic. During the crisis, poor nations could not access vaccines: "Despite appeals to humanitarian solidarity and to enlightened self-interest, almost all of the first billion doses of H1N1 vaccine produced in 2009 were allotted to 12 wealthy nations which

²⁸ Elbe, 482.

had made advance orders. Sanofi Pasteur and GlaxoSmithKline pledged 120 million doses to the WHO for distribution to poor countries, but even those pledges could be fulfilled only months after the pandemic had waned.”²⁹ In response, Laurie Garrett warned that events seemed to be proving Supari’s fears.³⁰ Other scholars have wrestled with the ethical problems that this experience raised. Even while the epidemic waned, developing countries remained uncertain if they might receive unused vaccine from wealthy countries.³¹

It is true that the World Health Organization made a substantial effort to push manufacturers and the developed world to make vaccine available for developing nations. But it was clear that this could not be the main tool to fight the epidemic, as Dr. Marie-Paule Kieny, the director of the Initiative for Vaccine Research at the World Health Organization stated in a 2009 interview:

Q: What happens if developing countries have only partial coverage?

A: Coverage will be partial and not only in developed countries. But we should not be “hypnotized” by vaccines. There are other measures, such as social distancing, school closure, avoidance of large gatherings, antibiotics and personal hygiene. This is not a disease like rabies, which is

²⁹ Khoon, p. 3.

³⁰ Khoon, p.3.

³¹ Marcel Verweij, “Health Inequities in Times of a Pandemic,” *Public Health Ethics*, 2:3 (2009): 207-209.

100% fatal: we are talking about a disease from which most people recover very well.³²

Dr. Marie-Paule Kieny also pointed out that the WHO had obtained commitments for 150 million doses of vaccine for developing countries from manufacturers, which was a major achievement. For developing countries, nonetheless, the 2009 pandemic served to accentuate their concerns that in the case of a truly lethal pandemic, they would be largely relying on the same public health measures that had been used during the 1918 pandemic. Of course, it was also true that this would be the case for citizens in developed countries. But concerns about global health equity remained, particularly in South-East Asia, which was the front-line of the global effort to contain avian influenza.

The main reason that developing countries could not obtain vaccine was the lack of production capacity and the existence of advance contracts. But another challenge was that in 2009 the United States government made the decision not to use adjuvants to stretch the supply of vaccine. By using adjuvants, which are chemicals that stimulate the immune systems' response to an antigen, vaccine manufacturers could make more vaccine available from existing production facilities. But policy makers in the United States worried that the public would not accept their use, despite the fact that Europe has a long history of employing them.

³² Anonymous, "WHO Supports fair access to influenza A (H1N1) vaccine," *Bulletin of the World Health Organization*, 2009, 87: 654.

In part, the U.S. decision may have reflected the political realities after a now-discredited study by British physician Andrew Wakefield, which suggested that there was a link between childhood vaccinations and autism. Many years and millions of dollars were spent discrediting this study, which was based on a small number (twelve) children, and which also seems to have been based on fraudulent data, according to an article in the *British Medical Journal* in 2011. Even though Wakefield was discredited, however, popular fears about vaccines remained. This likely shaped the U.S. government's decision not to use adjuvants in the novel H1N1 vaccine formulation. But this also meant that far more vaccine stock would be needed, which decreased the amount of vaccine that could be shared with developing countries. These nations found themselves to be in the position of depending upon decisions in the wealthy countries to receive vaccine. Fortunately, the pandemic had a relatively low level of lethality.

The Current Standoff

While Indonesia's position has moderated slightly since the 2009 H1N1 pandemic, the issue remains unresolved. The Minister of Foreign Affairs for Indonesia, Marty Natalegawa, expressed the position of developing countries during an interview on September 20, 2010, during which Laurie Garrett called in to ask him about the concept of viral sovereignty. He argued that work and resources from Indonesia contributed greatly to the development of vaccines, but Indonesia and

other poor countries had little chance of being able to benefit from them: “And I think what our present administration is doing is precisely striking a balance; how to ensure, on the one hand, we live up to our international obligations; but, on the other hand, . . . how we must make the issue of access to vaccines by developing countries a bit more prominent in international discourse, in terms of making sure that countries like Indonesia have –as a population within it, have access to vaccines.”³³

While Indonesia has continued to hold to its position, the position of developed nations has also remained the same:

Western countries, on the other hand, feared the human and economic impact of delayed detection of an emerging influenza pandemic and wish to avoid the precedent of acquiescing to ‘viral blackmail.’ The global health community’s reaction to these events has been split, because Indonesia’s actions are seen as undermining global influenza surveillance, but also as a clarion call to overturn long-standing inequities in the global pharmaceutical market. Both Indonesia’s actions and the various global actors’ responses have complex roots in self-interest, and domestic and international politics.³⁴

³³ Transcript, “A Conversation with Marty Natalegwa, Minister of Foreign Affairs, Republic of Indonesia,” *Council of Foreign Relations*, September 20, 2010. Accessed on January 31, 2011 from www.cfr.org/publication/22984/conversation_with_marty

³⁴ Harley Feldbaum, Joshua Michaud, “Health Diplomacy and the Enduring Relevance of Foreign Policy Interests,” *PLoS Medicine*, 7:4:

Harley Feldbaum and Joshua Michaud have argued that developing countries believe that the 2005 revisions of the International Health Regulations were undertaken so as to reflect the interests of the most powerful countries: “. . .the IHR were adopted because they served powerful state interests, and accordingly some developing countries view the IHR as an instrument of the foreign policy and national security interests of developed countries seeking protection from epidemics emanating abroad, and therefore as only an extension of age-old power politics.”³⁵ In short, there remain substantial concerns within the developing world, both regarding the overall structure of global health governance, as well as the independence of the World Health Organization.

Confidence regarding the integrity of the World Health Organization was further undermined in 2010, when Deborah Cohen and Philip Carter published an article in the *British Medical Journal*, which revealed that there serious conflicts of interest within the WHO. Some committee members who recommended stockpiling medications (Tamiflu and Relenza) and other measures to prepare for a pandemic were revealed to have financial ties to the pharmaceutical companies most likely to benefit from these measures. For the WHO’s critics, this revelation created issues of transparency in the WHO’s policymaking

e1000226.doi:10.1371/journal.pmed.1000226, 7.

³⁵ Feldbaum and Michaud, 7. For more information on IHRs see Lawrence O. Gostin, “International Infectious Disease Law: Revision of the World Health Organization’s International Health Regulations.” *Journal of the American Medical Association*, June 2, 2004, 291:21, 2626 (double check page number).

process.³⁶ In particular, they questioned the WHO's decision to declare the 2009 H1N1 outbreak a "pandemic" despite the relatively low mortality rates. They also pointed to concerns about the political influence held by industry-funded groups such as the European Scientific Working Group on Influenza. Was the WHO too tightly connected to major pharmaceutical corporations to create disinterested health policy?

In a larger sense, most observers have agreed that the reason that global health governance has not changed because the status quo favors the interests of the most powerful nation-states. David Fidler argued that a new framework for global health governance appeared unlikely in 2010: "The prospects for such a framework are not, however, promising, because the national interests of most developed states vis-à-vis dangerous influenza strains favor retaining the existing imbalanced, reactive, and ad-hoc approach to vaccine access."³⁷

Indonesian authors have made the same point: "Poor countries have no bargaining position, because their participation in the production of these products are not valued as they are 'just' natural resources (clinical specimens, viruses, and other microbes); on the other hand the industrialized countries' contributions are highly valued because

³⁶ Deborah Cohen, Philip Carter, "WHO and the Pandemic Flu 'Conspiracies.'" *British Medical Journal*, June 2010, 340: 2912.

³⁷ David P. Fidler, "Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza, H1N1." *PLoS Medicine*. 7(5): e1000247. Doi:10.1371/journal.pmed.1000247.

they are human invented technology.”³⁸

This perception might change rapidly in an avian flu pandemic with greater lethality than its 1918 forerunner. In that case, would countries Egypt or Indonesia share viral seed stocks in time to create vaccines in the developed world? Or might they be tempted to withhold stocks as a bargaining tool to obtain more vaccine? What would be the international political costs if the U.S. did not choose to use an adjuvant, which reduced vaccine supplies for other nations, during a severe pandemic? The existing order seems tolerable only because the international community has not faced a truly severe public health crisis.

In the 1990s, HIV/AIDS came to be seen as a security issue, because of the instability that the disease might foster in developing countries.³⁹ This argument was made from within a traditional, realist security perspective. Within in the framework of human security, which focuses primarily on threats to the individual rather than to the state, influenza is clearly a preeminent security challenge, because few dangers could cause such major casualties, short of nuclear warfare or bioterrorism. From this viewpoint, influenza preparation is more than a solely health concern, and merits substantial resources and attention to address. In 2005 then Senator Barack Obama argued in the *New York Times* that avian influenza posed a security threat to the United

³⁸ Sedyaningsih et al, 487.

³⁹ Harley Feldbaum, Kelly Lee, Preeti Patel, “The National Security Implications of HIV/AIDS,” *PLoS Medicine*, 2006, 3(6): e171. Doi:10:1371/journal.pmed.0030171.

States.⁴⁰ But there are dangers to securitizing health issues, as the drug wars in Mexico and Colombia illustrate. If they defied the WHO, would nations such as Indonesia be defined as rogue states in a new international health order? Currently, the WHO has no enforcement ability regarding International Health Regulations, which makes such concerns appear unrealistic. But Stefan Elbe has made the argument that it was precisely because avian flu was increasingly viewed in terms of security that the standoff between the West and Indonesia became so severe.⁴¹ This approach may seem attractive because of both the resources and governmental attention that it can help to bring to a problem.⁴² But if Elbe's argument is correct, then the issue is best dealt with as an issue of global health governance.

The Rise of Transnational Alliances

At the same time, global health raises larger issues that lead to questions about the nation-state as the main actor in international politics. Is the nation-state the best level of analysis for global health problems? Niam Stephenson has argued that people no longer look solely to the nation state for "rights and representation" but rather to an array of other transnational actors. In the era of globalization, questions of sovereignty and health create new perspectives on the international order. Stephenson suggests that the WHO has been a

⁴⁰ Elbe, 478.

⁴¹ Elbe, 476-485.

⁴² Elbe, 479, 482.

weakening political actor because of decades-long trend in which it is underfunded. As the WHO has worked to securitize health in order to respond to international health challenges, new political actors are becoming involved in these affairs, which he called “aggregates.” These aggregates are alliances between varying actors –developing countries and NGOs, the World Health Organization and pharmaceutical companies- that mobilize around an ideology to achieve their health objectives. Stephenson suggests that this international order is shaped by neoliberal objectives, in particular the need to ensure the unimpeded flow of trade goods, in a manner that can conflict with health goals, such as the need for quarantine. In this context, Stephenson suggests that nationalist rhetoric, such as that of Supari, is employed to challenge transnational powers and the neoliberal agenda. As such, Indonesia’s position represented more than a challenge to influenza preparation. Developing countries fear that pharmaceutical companies are driving global health policy, as a new market for growth. But current influenza preparations often exclude developing countries, by such means as advance contracts, as the H1N1 pandemic in 2009 suggested. From this perspective, Indonesia’s effort represented an alternative alliance for global health policy –one between a developing country and a vaccine maker, Baxter- rather than the existing “aggregate” between the WHO and

global pharmaceutical corporations.⁴³

Stephenson's argument raises key questions. In what way does the securitization of health discourse challenge existing ideas about the nation-state, and what groups does it empower? When we discuss health security, do we mean security for the individual or the state? Why has sovereignty been at the core of these discussions, and which entity has the right to assert authority over biological samples? Is the concept of "aggregates" a useful one to understand the emerging players in global health? To what extent do neoliberal economic ideals shape current policy-making by health actors such as the WHO? And perhaps most of all, who should people look to, in order to make decisions for global health? In the long term, policy-making as part of pandemic preparations will have to address these questions. At the same time, in the short term there are also some practical, hard questions to answer. What then, should global health actors, such as the World Health Organization, do in the face of a pandemic?

Public Health Policy

Practical issues bedevil preparation efforts, particularly concerning advance contracts for vaccines. Given current structures, if all organizations and states act in a rational fashion, they may make choices that could keep tens of millions of vaccine doses from use in a

⁴³ This paragraph is based on Niam Stephenson, "Emerging Infectious Disease/Emerging Forms of Biological Sovereignty," *Science, Technology and Human Values*, 2010, 1-22.

pandemic. A series of public health steps are needed to increase confidence in the WHO, to respond to the demands of developing countries for greater access to vaccines, and to ensure the continued access of the WHO to viral seed stocks. Many authors have made recommendations for improving the current situation, which the following list builds upon:⁴⁴

1. The Material Transfer Agreements used by the World Health Organization should specify that if viral seed stocks are used by a corporation to produce vaccines, then a portion of those vaccines must be supplied to the country of origin at a reasonable price during a pandemic.
2. The World Health Organization should ensure that all people involved in the formulation of health policy related to influenza are not retained or employed by vaccine manufacturers or pharmaceutical corporations that produce medications to treat influenza.
3. The WHO should request that advance contracts for influenza vaccine only be adopted only if the contract states share a fraction of the vaccine produced with developing countries.
4. The WHO should request that developed countries should dedicate a portion of foreign aid to supporting the stockpiling of

⁴⁴ See Mullis, 964-967.

- medications and vaccines for influenza in the developing world. In addition, the World Bank should prioritize loans to increase not only vaccine production capability in developing countries, but also their surveillance and reporting infrastructure. In some countries, such as Brazil, the World Bank's support created dramatic changes in the efforts to fight HIV/AIDS. A targeted effort could achieve the same with preparations for influenza.
5. Developed countries -in particular the United States- should conduct research on adjuvants, to identify those that could be used with confidence in a pandemic. These nations should commit the use of adjuvants in a pandemic, in order to ensure that vaccine supplies are stretched to the maximum extent possible.
 6. Developing nations should commit to sharing viral seed stocks with the World Health Organization in as rapid a manner as realistically possible, and to support the World Health Organization's International Health Regulations.

Conclusion

The global community has recently evaded a number of disasters, such as the 2003 SARS pandemic, which was ultimately contained, and the 2009 influenza pandemic, which proved to have a relatively low mortality rate. Still, we cannot expect that we will

continue to enjoy such good fortune. While issues of global health equity may appear to be abstract questions, in a health crisis they would rapidly escalate into diplomatic crises. For this reason, there is a pressing need to resolve these questions before a crisis strikes. As Stefan Elbe has argued, Indonesia's protest has led to some changes: "Already, the WHO has taken some steps to accommodate the demands of Indonesia and other developing countries, including the development of a system for tracking the movement of shared H5N1 virus samples, and exploring the feasibility of creating a stockpile of vaccines that developing countries could draw on."⁴⁵ While these technical steps are helpful, they do not address the larger questions that influenza pandemics entail.

Part of the reason that this political dispute has been so difficult is that it has challenged our existing assumptions about the global order, which is predicated on the notion that nation-states are the key political actors, which should act on a rational basis to defend their national interests. The trouble with this assumption is two-fold. Global health problems can only be addressed through collaboration, which is unlikely to be achieved if the key actors are the nation-states alone. Second, there are key transnational actors, in particular big pharmaceutical companies and vaccine manufacturers, which are global actors in their own right. These actors are capable of entering

⁴⁵ Elbe, 483.

into commercial and research partnerships with both nation-states and international organizations in a manner that can profoundly impact individuals' ability to access both vaccines and medicines. Stephenson points also what has taken place with HIV/AIDS over the last decade, during which huge amounts of money have been funneled by what he calls "vertical actors," such as the World Bank and non-governmental organizations.⁴⁶ In this context, health cannot be considered outside the context of larger global political questions. Before the next crisis comes, as it will, the global community needs to address not only the technical questions that are entailed, but also the broader philosophical issues, in order to create a new framework for pandemic preparedness.

⁴⁶ Stephenson, 13.