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### **Indonesia, Power Asymmetry, and Pandemic Risk**

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# INDONESIA, POWER ASYMMETRY, AND PANDEMIC RISK

## The paradox of global health security

*William L. Aldis & Triono Soendoro*

In late 2006 the world was on the brink of a catastrophic pandemic due to the avian influenza (“bird flu”) virus H5N1. It was essential to conduct genetic studies of new viral strains isolated from human cases and to get a head start on vaccine development for those strains that appeared to have the highest pandemic potential. At this critical moment there was a breakdown in the global system for sharing of virus isolates.<sup>1</sup> Indonesia, without access to vaccines and antiviral medications and acting in desperation, suspended sharing of viral isolates with the World Health Organization (WHO) and its Collaborating Centers. International reaction was harsh and immediate.

Here we analyze Indonesia’s position. We argue that the virus sharing episode, not fully resolved 7 years after it erupted into a global crisis, has implications for health security far beyond sharing of viruses and benefits. If the geopolitical issues surrounding this episode are not properly understood and resolved, we can expect ominous consequences far beyond avian influenza. We will see that embedded in the geopolitics of virus and benefit sharing there is a paradox: when countries pursue security on their own narrowly defined terms while disregarding the vital interests of others, all countries become less secure.

We will give special attention to issues of ownership, specifically ownership of biological materials and derivatives; and with it, rights to the products of that ownership. Central to these concerns are material transfer agreements, or terms and conditions of transfer, in the context of a market-based political economy (Chan & de Wildt 2007: 1–6). While only a small part of this complex story, these issues and their relationship to access, possession, and economic exploitation of knowledge can serve as an analytic frame or entry point to understand the events that precipitated Indonesia’s decision to suspend sharing of H5N1 isolates with the global system in early 2007. Why did the key actors (nonindustrialized countries, the WHO, industrialized countries, and commercial interests) behave the way they did? And most important, what does this tell us about potential fracture lines in fragile global relationships that are essential to maintain global health security generally?

We will not attempt a detailed epidemiological account of the global H5N1 avian influenza outbreak or an exhaustive history of the continuing controversy over sharing of virus isolates and sequences and benefits thereof. Likewise we will not enter into the debate on how the International Health Regulations and the Convention on Biological Diversity apply to sharing of viruses and benefits. These issues have been well discussed elsewhere (Fidler, 2008; Irwin 2010;

Sedyaningsih et al. 2008; World Health Organization 2011a). Instead we will identify key contentious points that have general significance for global health security. After a review of the events leading up to Indonesia's decision to cease virus sharing, we will attempt to answer the following questions about this extraordinary situation:

- 1 Why did Indonesia take the extraordinary step of suspending transfer of H5N1 virus isolates to WHO? Could the crisis have been avoided or quickly resolved? If so, how?
- 2 What were the underlying issues, and what steps have been taken to resolve them?
- 3 What steps can be taken now to protect the vital interests of non-industrialized or low-income countries?
- 4 Are there wider implications for global health security? Could similar breakdowns occur for other pandemic risks, or unrelated global health threats?

### Background to the crisis

Human disease associated with influenza A subtype H5N1 reemerged in January 2003 for the first time since an outbreak in Hong Kong in 1997. Three people in one family were infected after visiting Fujian province in mainland China and two died (Peiris et al. 2004: 617–619). By late 2006, there had been 263 human cases and 158 deaths in nine countries, with virological studies showing considerable genetic variation among strains isolated from human cases. The case fatality rate in Indonesia was an extraordinary 81% in 1995 and 1996 – among the highest death rates recorded for any human pathogen (Sedyaningsih et al. 2008: 484). However the virus was poorly transmissible between humans, with only rare cases of probable human-to-human spread (Olsen et al. 2005: 1799; Ungchusak et al. 2005: 333–340). Nevertheless virologists were aware that the genetically unstable H5N1 virus could, through genetic reassortment or mutation, transform into a strain with the lethality of H5N1 and the transmissibility of human Influenza A: the pandemic virus. Prompt genetic analysis of isolates from human cases was urgently required and, when appropriate, preparation of attenuated (weakened) seed viruses for vaccine production.

It was at this critical juncture that Indonesia suspended sharing of new H5N1 isolates with WHO's Collaborating Centers, where genetic analysis and production of attenuated seed strains for vaccine production were carried out.

### The evolving virus sharing crisis

The international media reaction to Indonesia's decision to withhold viral isolates was intense, polarized, and revealing. In an editorial titled "Recipe for a Pandemic," the *Wall Street Journal* argued that "Supari (Indonesia's Minister of Health) asserts that Indonesian bird flu is a form of intellectual property, from which the country should benefit. By hoarding samples and trying to tinker with the financial incentives that drive pharmaceutical innovation, Indonesia is endangering everyone" (Wall Street Journal 2008). In an opinion piece published in the *Washington Post*, the respected U.S. diplomat Richard Holbrooke and the science journalist Laurie Garrett aggressively criticized Indonesia's claim to what they called "viral sovereignty." The authors described the idea that sovereign states could exercise ownership rights over samples of viruses found in their territory as "ludicrous" and "dangerous folly" (Holbrooke & Garrett 2008). The U.S. Secretary of Defense dismissed concerns raised by Indonesia's Minister of Health over the possible military use of H5N1 as "nutty" (United Press International 2008). (However, it was later revealed that the U.S. military did have an extensive system of influenza virus collection operating in parallel with WHO's influenza surveillance system in 56 countries, Hammond 2008a.)

In much of the negative international reaction there is an assumption that Indonesia's actions were arbitrary, inexplicable, or motivated by a desire for financial gain. The U.S. Secretary for Health and Human Services (equivalent to Minister of Health) was quoted as saying that the Indonesian Minister of Health's "bottom line appeared to be . . . share samples, get paid" (Associated Press 2008). Few of these negative stories presented Indonesia's position or acknowledged the fact that the country did have legitimate and urgent public health concerns that were not being addressed by the existing mechanisms for sharing viruses and accessing benefits including vaccines and antiviral drugs. Epidemiologists also recognized, of course, that the source country of an emergent pandemic pathogen would be the epicenter of an evolving pandemic and would face the highest mortality early on.

Other observers were more sympathetic to Indonesia's situation. An editorial in the respected British journal *The Lancet* noted that "To protect the global population, 6.2 billion doses of pandemic vaccine will be needed, but current manufacturing capacity can only produce 500 million doses . . . most developing countries would have no access to vaccine during the first wave of a pandemic and possibly throughout its duration. . . . Indonesia's move to secure an affordable vaccine supply for its population is understandable" (Lancet 2007: 532).

Why did Indonesia take the extraordinary step of suspending sharing of H5N1 isolates with WHO's Collaborating Centers? From mid-2006 onward, Indonesia received a series of shocks that led it to question the sincerity of WHO and the international community. In violation of WHO guidelines, studies on H5N1 strains from Indonesia were reported at international meetings without prior participation or consultation with Indonesian scientists (or in some cases with notification only hours before the presentation). Indonesian scientists were asked in a *pro forma* fashion to become coauthors on papers already written by international scientists, who, to the surprise of Indonesia's scientists, had been given access to viral isolates sent by Indonesia to WHO (Sedyaningsih et al. 2008: 485). This is not a trivial question of publication rights: Indonesian virologists and public health officials were left in the dark on scientific research on lethal viruses actively circulating in their country.

Then it was revealed in early 2007 that an Australian company had developed and patented a vaccine from an Indonesian H5N1 strain (Fidler 2008). More disturbing, officials in WHO's Regional Office for South-East Asia and in Indonesia subsequently discovered that WHO's 2005 guidelines on sharing of influenza isolates, titled "Guidance for the Timely Sharing of Influenza Viruses/Specimens with Potential to Cause Human Influenza Pandemics," had been mysteriously deleted from the WHO website. These guidelines required that "designated WHO Reference Laboratories will seek permission from the originating country/laboratory to co-author and/or publish results obtained from the analyses of relevant viruses/samples . . . there will be no further distribution of viruses/specimens outside the network of WHO Reference Laboratories without permission from the originating country/laboratory." (Although these guidelines have been deleted from WHO's public records, the authors have copies in their files that are available on request.)

Adding further to Indonesia's anxieties, WHO admitted that further patents had been sought on modified versions of influenza (H5N1) samples shared through the Global Influenza Surveillance Network (GISN) without the notification or consent of the countries that supplied the samples, contrary to the inexplicably deleted WHO guidelines (Fidler 2008: 88; Khor 2007b; Sedyaningsih et al. 2008: 486). A flood of patents and patent applications on pandemic-prone influenza viruses isolated in Indonesia, Thailand, and Vietnam, first detected in 2007 (Hammond 2007), has accelerated since (Hammond 2011). Even the Centers for Disease Control in Atlanta, USA, a WHO Collaborating Center, was discovered to have claimed patents on vaccines containing gene sequences from H5N1 influenza viruses contributed to WHO by Indonesia (Hammond

2008b). Source countries and their scientists were, and remain, uninformed on the content and purposes of these patents and others taken by commercial enterprises (Novartis, GlaxoSmith-Kline, Temasek Life Sciences, & others) on materials that they donated to WHO with the understanding that they would be used for public health purposes.

Officials in Southeast Asian countries began to ask the obvious question: would affected countries be able to obtain vaccines produced from the isolates they submitted to WHO? When asked how countries could obtain vaccines from manufacturers, the response of the WHO Assistant Director General for Communicable Diseases was not reassuring: “That will be necessary for the countries to negotiate. WHO is not involved in financial negotiations, either in selling viruses or buying vaccines. Countries will negotiate bilaterally with vaccine manufacturers” (World Health Organization 2007a).

The cumulative effect of all of this was a loss of trust in the WHO secretariat by many of its member states. Loss of trust in WHO on this issue is not a trivial matter. In an extraordinary development, member states from nonindustrialized countries insisted that the record of the first intergovernmental meeting on sharing of viruses and access to benefits contained an acknowledgement that “there has been a breakdown of trust in this essential system of the international collaboration and collective action”, and that “the current system does not deliver the desired level of fairness, transparency and equity” (Irwin 2010; World Health Organization 2007b). There are few if any other instances when a significant number of WHO member states concluded that the WHO secretariat had not acted in the best interests of the most vulnerable countries.

Indonesia’s radical step in refusing to share H5N1 isolates had a specific objective: to ensure that the country would have access to a portion of the vaccines, antiviral drugs, and diagnostic technologies that would be derived from the viral isolates collected by Indonesian scientists and transmitted in good faith to WHO’s Collaborating Centers. Contrary to incomplete reports in the international media, the country was willing to resume submission of specimens if they could be assured of access to some of the benefits.

Indonesia’s position, stated early in the crisis in February 2007, was specific, consistent with current practice, and actionable:

Indonesia will insist on a material transfer agreement (MTA) before sending the Indonesian strain of bird flu virus to foreign laboratories to prevent them from being used for commercial purposes. . . . We agree to send the virus to the WHO with new conditions or mechanisms approved by both parties as well as by other developing countries. Until then, we won’t share the samples. . . . The organization [WHO] sometimes forgets the good of the people in general and we want to change that.

(Khor 2007a)

If this proposal had been taken seriously, it would have had been a good starting point for resolving the crisis.

An MTA is a document that is signed by both provider and recipient of scientific or other materials. It sets out conditions of transfer, and usually includes provisions on how the material will be used, restriction on further transfer without prior notification of the provider, and limitations on commercial use. In essence it maintains control – de facto ownership – of the material in the hands of the provider. MTAs are routinely required for shipment of human biological materials or other hazardous materials in the United States and in Europe. In Indonesia, MTAs have been required in Indonesian law since 1995 (Ministry of Health Republic of Indonesia 1995; Ministry of Research and Technology Republic of Indonesia 2006) and were further reinforced

by a 2006 provision that government officials who failed to comply with this and other domestic laws could face 13 years of imprisonment. Clearly there was an international precedent, indeed a requirement, for use of MTAs when transporting hazardous biological materials.

Indonesia's analysis of the situation facing the populations of nonindustrialized countries, and their rationale for demanding an MTA, was clearly stated in international meetings convened to resolve the problem (Republic of Indonesia 2007). These statements were routinely ignored in the international media. Several member states, led by the United States, vigorously opposed Indonesia's proposal to apply a material transfer agreement (Irwin 2010). This refusal is revealing. Industrialized countries argued that applying an MTA was inappropriate in an evolving pandemic situation and would slow the process of developing a vaccine. This was clearly a false argument, since WHO Collaborating Centers and commercial vaccine producers *required* MTAs for all further transfer of isolates and seed viruses (Sedyaningsih et al. 2008: 487).

There is little argument about rights of ownership of biological materials. The only question is *ownership by whom*.

We will never know what form a transparently negotiated MTA would have taken, had it been negotiated at this point. Certainly it would have contained guarantees that the source country and other nonindustrialized countries would have access to vaccines and other benefits. Indeed, the WHO MTAs (redesignated as standard material transfer agreements or SMTAs) that emerged after 6 years of often bitter argument, and over the resistance of several industrialized countries, contained some of the features that should have been negotiated in early 2007 (World Health Organization 2011b: 30–36).

Six years of meetings and rancorous negotiations followed the industrialized countries' refusal to accept Indonesia's proposal to negotiate a material transfer agreement. The issue was debated in intergovernmental meetings, at WHO's Executive Board and World Health Assemblies, in high-level technical meetings, and in open-ended working groups. The outcome was a Pandemic Influenza Preparedness Framework, a Partnership Agreement (a mechanism to fund WHO's influenza activities in part through industry contributions), and two "Standard Material Transfer Agreements": SMTA 1 and SMTA 2 (World Health Organization 2011b: 3–6; World Health Organization 2011c: 2–10; World Health Organization 2013: 1–10). While all of these products are important, we will restrict this discussion to the two SMTAs.

SMTA 1 is used for transfer of influenza viral isolates and other "PIP biological materials"<sup>1</sup> from originating countries to WHO and its Collaborating Centers and for all transfers within WHO's GISRS (Global Influenza Surveillance and Response System). For our purposes, a key clause in the SMTA 1 is in Article 6 (Intellectual Property Rights), which states: "Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials." This is an interesting provision. While most MTAs are written to ensure that the originator (provider) of a substance or product retains ongoing control over its further use, commercial application and so forth, this MTA is intended to have the opposite effect.

SMTA 2 is used for transfers of materials to entities outside the WHO GISRS. These entities include vaccine manufacturers. Only one SMTA 2 has been negotiated so far, with the vaccine producer GlaxoSmithKline (WHO/GlaxoSmithKline 2013: 1). This SMTA contains many positive features, including commitments by GSK to donate a portion of its pandemic vaccine production to a WHO stockpile that is provided for in the Pandemic Influenza Preparedness Framework. However, there are several significant omissions. There are no limitations on patenting or use of materials or derivatives. There is a provision for "acknowledging the contributions of WHO laboratories in presentations and publications," but no requirement to involve national or WHO scientists in research, for example in field trials on vaccine efficacy, or to inform WHO or its member states of the existence of clinical trials or their findings. It is disappointing that WHO

accepted an SMTA 2 that did not have provisions that are appropriately required for WHO's own affiliated laboratories (World Health Organization 2011b: 30–31).

Perhaps the most surprising feature of the GlaxoSmithKline/WHO SMTA is the dispute resolution process. Disputes that cannot be resolved between the parties will be referred to the commercially funded International Chamber of Commerce and presumably handled through the ICC's International Court of Arbitration. It is extraordinary that a United Nations agency would submit itself to binding arbitration by a private sector body, and it is far from certain that such a body will be capable of dealing with the critical public health issues likely to arise in disputes.<sup>2</sup>

Viewed from the perspective of nonindustrialized countries, especially those at the likely epicenter of an emerging pandemic, what has been gained and lost after 6 years of negotiation over sharing of viruses and benefits? While the WHO's Pandemic Influenza Preparedness Framework and standard material transfer agreements do contain provisions for antiviral and vaccine stockpiling of vaccines and other benefits (including, as an option, licensing for vaccine production in "developing" countries) there is no specific provision that the source countries of the original viral isolates (the epicenter for a pandemic) will receive sufficient vaccines and other supplies, and the quantities reserved for low-income nonindustrialized countries are low in proportion to their populations and their likely pandemic exposure.

A simple "thought experiment" illustrates the inequitable situations of industrialized and nonindustrialized countries on the virus and benefit sharing issue. Imagine this scenario:

*An outbreak caused by a novel viral pathogen occurs in the United States, with many cases and deaths. A similar viral strain had been studied in a WHO Collaborating Center in China, and this laboratory has advanced knowledge and techniques relevant to this virus. The US is requested to forward virus isolates to the Chinese Collaborating Center without conditions and surrendering all intellectual property claims, as required by WHO's SMTA 1. The Chinese WHO CC would quickly produce a seed virus and transmit it to commercial producers of its choice in China or elsewhere, utilizing a WHO SMTA 2 transfer agreement. There would be no guarantee that the US would receive any vaccines.*

Would the United States agree to forward virus isolates to WHO under these conditions? Not likely. But these are the terms imposed on countries like Indonesia when they submit viral isolates to WHO under the SMTA 1.

## **Wider implications for global health security**

### *The Erasmus episode*

Whatever fragile level of trust may have been emerging after agreement on the Pandemic Influenza Framework was shaken at the 2013 World Health Assembly. The Health Minister of Saudi Arabia complained that Erasmus University in the Netherlands had obtained, sequenced, and developed a MTA for the virus responsible for the newly described (and highly lethal) Middle East Respiratory Syndrome (MERS). While Erasmus University had the legal right to proceed as they did, doing so without prior notification of the Saudi government (and, needless to say, without any consideration of sharing of benefits with the source country) was ethically questionable.

The virus that causes MERS is a coronavirus, not an influenza virus, and therefore not covered under the provisions of the WHO Pandemic Influenza Preparedness Framework. However, one

would have hoped that the Erasmus laboratory, whose head is a longtime consultant to WHO and a member of WHO's strategic advisory group on influenza, would have behaved differently in this situation. The Erasmus group claims that the virus is being made freely available to researchers, but Erasmus University maintained tight control on further use of the virus through an MTA – “The provider retains ownership of the material” (Office of the University Counsel University of North Carolina/Erasmus University 2013: 2–6). There is little doubt that the interests of international researchers – and next in line, commercial interests – are better protected than those of vulnerable populations in the Middle East and elsewhere (Garrett & Builder 2013; Hammond 2013; Kupferschmit 2013).

### ***Protecting the vital interests of nonindustrialized countries***

Trust and transparency are rare commodities in the geopolitics of global health. Nonindustrialized countries at risk from global health threats should enter negotiations and agreements with their eyes open.

Hoffman (2012) analyzed the inequalities of influence between states in global decision making. More important, he proposed a series of steps that could be taken to remedy the problems. He starts with the observation that international organizations (including WHO):

assert superordinate normative authority based on having egalitarian governance structures. However, when defining equality with respect to states' real-world influence in determining substantive outcomes, it is evident that there is an equality-influence gap between the rhetoric of parity among states and the reality of international politics. This is problematic because it undermines trust in those international institutions that falsely claim to embody equality among states when empirically they do not.

Hoffman then identifies three main causes of this disproportional influence among states in global decision making: (a) external imbalances in political capital; (b) internal economic barriers; and (c) surreptitious influence through non-state actors. All of these factors were operative in the Indonesian virus-sharing crisis.

Finally and most significant, Hoffman points to six initiatives as ways forward: 1) building capacity for leadership in global advocacy; 2) supporting global networks owned by developing countries; 3) equalizing multiparty partnerships; 4) facilitating evidence-informed global decision making; 5) enhancing accountability and independent evaluation; and 6) encouraging further discussion on institutional reforms (Hoffman 2012: 421–432).

Each of these six initiatives deserves further discussion, but here we will briefly explore the first and second, which are closely related and can be discussed together. For these two initiatives, nonindustrialized countries can operate independently of their more powerful neighbors and can expect immediate gains.

### ***Building capacity for leadership in global advocacy and supporting global networks owned by developing countries***

In global fora the industrialized countries are often in the lead. They are confident. They have skilled diplomatic, legal, and technical staff. They know how to network. Like-minded high-income countries come together to plan their moves and countermoves well in advance of important international meetings. Nonindustrialized countries have many of the necessary



skills, but their qualified negotiators and technical experts are sometimes working in isolation. Although there are exceptions (the potent triangulation of Brazil, India, and South Africa on pharmaceutical trade negotiations is an example), there have also been many missed opportunities.

Nonindustrialized countries can mobilize on an ad hoc basis for a specific issue, as was attempted with some success in the Indonesia virus sharing episode; but a more structured caucus approach (e.g., the G-77 and the G-22 groups) provides more scope for policy, tactical synergy, and capacity building. For some issues, a different mix of countries or a different policy or technical orientation is needed. The treaty-based South Centre, an intergovernmental organization with 55 member states, is an example. The South Centre is respected for its strong intellectual and policy support to its members (South Centre 2013).

### ***The paradox of global health security***

The World Health Organization's member states have negotiated the issues of sharing of pandemic-potential viruses and benefits with great difficulty and uncertain results. The process was marked by an absence of trust and transparency.

Beyond pandemic preparedness, we encounter difficult questions at the intersection of public health and national security on the road to global health security. A healthy relationship between all nations (or at least between most nations, most of the time) is a precondition for global health security. While this will seem obvious to some, many global negotiations and transactions have been based on the implicit assumption that more powerful nation states are in a position to dictate terms to the less fortunate and should take advantage of the opportunity when it arises. This was attempted in the case of Indonesia and sharing of H5N1 isolates, with potentially catastrophic results.

This is the paradox of global health security. Countries that pursue their own narrowly conceived national security and commercial interests while disregarding the vital interests of other countries will weaken global – and their own – health security in the long run, a danger that was narrowly averted in the Indonesia virus sharing episode. The problems created by a narrow “securitized” approach to global health are not limited to influenza virus sharing: “A key lesson to emerge from the international virus sharing controversy is . . . that a securitized response to infectious disease management can also have unanticipated consequences in terms of further complicating international health cooperation” (Elbe 2010). While this lesson is obvious for a problem like pandemic disease, for which the entire world population is in a common risk pool, it applies equally to other problems such as nuclear safety, arms control, or any of many other security threats for which global cooperation and agreement are essential.

### **Notes**

- 1 In this paper we refer to influenza viral isolates. WHO documents and agreements refer to a broader range of influenza related materials, collectively termed “PIP (pandemic influenza preparedness) materials.” These include “human clinical specimens; virus isolates of wild type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment.”
- 2 By submitting to binding arbitration (dispute resolution) by a private body, WHO appears to have taken the extraordinary step of waiving protections guaranteed to it by the Convention (treaty) on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947.

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