

Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia

Endang R Sedyaningsih,^{1,2}*DrPH*, Siti Isfandari,^{1,2}*MA*, Triono Soendoro,²*PhD*, Siti Fadilah Supari,³*DR*

Abstract

Introduction: As the country hardest hit by avian influenza, both in poultry and in human, Indonesia's decision to withhold samples of avian influenza virus A (H5N1) has fired up a global controversy. The objective of this paper is to describe the position taken by Indonesia in the events leading to the decision and in those conducted to resolve the situation. **Methods:** The sources for this paper are the Indonesian human influenza A(H5N1) case reports and study results, summaries, minutes and reports of national and international meetings of virus sharing, and other related Indonesian and WHO documents. **Results:** The International Health Regulations 2005 have been applied in different ways based on different interpretations. While one party insists on the importance of free, non-conditional, virus sharing for risk assessment and risk response, Indonesia – as supported by most of the developing countries – stresses on the more basic principles such as sovereignty of a country over its biological materials, transparency of the global system, and equity between developed and developing nations. **Conclusions:** This event demonstrates the unresolved imbalance between the affluent high-tech countries and the poor agriculture-based countries. Regional, global and in-country meetings must continue to be conducted to find solutions acceptable to all.

Ann Acad Med Singapore 2008;37:482-8

Key words: H5N1, IHR 2005, MTA, Sovereignty

Introduction

Since July 2005 to December 2007, Indonesia has reported the highest number of influenza A (H5N1) human cases in the world, i.e., 116 cases with an extremely high fatality proportion of 81% [National Institute of Health Research & Development, Indonesia Ministry of Health, unpublished report]. Those patients were reported from 12 out of 33 provinces (Fig. 1). Among poultry, influenza A virus (H5N1) was identified in Indonesia since December 2003, and in December 2007 – 4 years later – 31 of 33 provinces had reported outbreaks of H5N1 in poultry, resulting in more than 16 million poultry deaths, from sickness and culling (Indonesian Ministry of Agriculture, unpublished data).

Following the policy of the Ministry of Health (MOH), suspect human H5N1 cases had been referred to one of the 100 designated Avian Influenza Referral Hospitals. During hospitalisation, a series of clinical specimens (usually throat and nasal swabs and, if available, endotracheal

aspirates and washes from intubated patients, and lung biopsies from deceased patients) were obtained and sent for testing at laboratories in Jakarta. Testing included detection of H5-specific viral RNA by conventional and real-time reverse-transcriptase polymerase chain reaction (RT-PCR), and detection of H5N1 antibody in sera by a modified horse red blood cell hemagglutination inhibition (HI) assay.¹

During the first one and a half years, Indonesia had sent all clinical specimens to a couple of international laboratories participating in the World Health Organization (WHO) global influenza surveillance network for diagnostic confirmation and risk assessment purposes. Since January 2007, however, the Government of Indonesia has decided to withhold the specimen (virus) sharing practice and to conduct the case confirmation within the country.

The objective of this paper is to describe the succession of incidents which had induced this drastic decision, the arguments in support of Indonesia's protest against the established more-than-50-year-old WHO system, as well

¹ Center for Biomedical and Pharmaceutical Research and Development, Indonesia

² National Institute of Health Research and Development, Ministry of Health, Jakarta, Indonesia

³ Ministry of Health, Jakarta, Indonesia.

Address for Correspondence: Dr Endang R.Sedyaningsih, NIHRD, Jl. Percetakan Negara no.29 Jakarta 10560, Indonesia.

Email: esedyani@indo.net.id

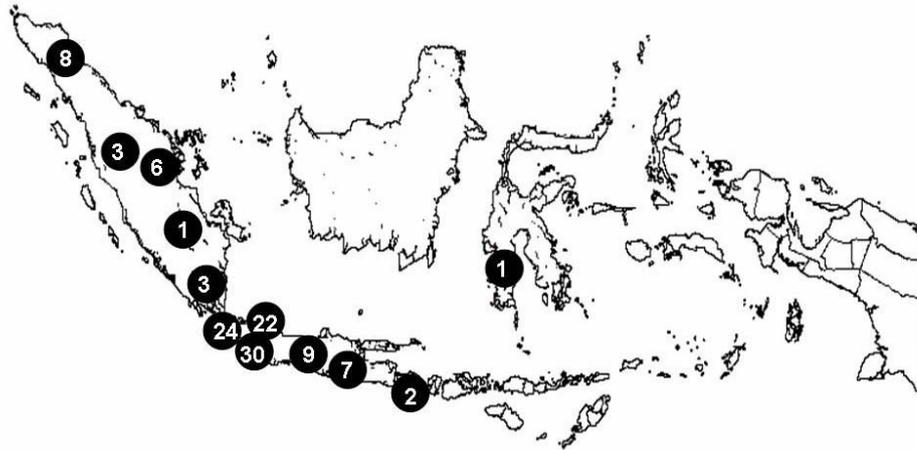


Figure 1. Provinces in Indonesia with H5N1 human cases (July 2005 – December 2007) Numbers are numbers of H5N1 positive cases

as Indonesia’s demand for a new and better mechanism for global risk assessment.

Methods

The sources for this paper are the Indonesian human influenza A (H5N1) case reports and study results, summaries, minutes and reports of national and international meetings on virus sharing, and other related Indonesian and WHO documents.

Epidemiological, clinical and virological data of the H5N1 human cases were collected and analysed by the MOH. Results were published and presented in several national and international publications²⁻⁵ and conferences in collaboration with international institutions. Most of the international collaborative studies are still in progress.

Chronological events that directed Indonesia to its current policy are also well documented.⁶ Several national, regional and international meetings have been organised to resolve the virus sharing issue.⁷⁻¹⁴ Those summaries, minutes, and reports, as well as other documents were studied and used as the basis of this paper.

Results

Epidemiology of Human Avian Influenza Infection in Indonesia

Indonesia reported the first human influenza A (H5N1) case in July 2005. A cluster comprising 3 blood-related family members of moderate socio-economic status died with severe progressive pneumonia, without a clear history of contact with sick or dead poultry.³ Following these first cases, from September 2005 till May 2007, Indonesia had reported an average of 5 new avian influenza cases per month. Despite the control measures conducted in the agriculture sector to diminish H5N1 among poultry, from June 2007 up to December 2007, the confirmed H5N1 human cases were still reported at an average of 3 patients per month (Fig. 2), and the affected provinces have increased from 4 in 2005, to 9 in 2006, and to 12 in 2007. Particularly in Tangerang district and municipality, Banten province, which is adjacent to the western part of Jakarta, the case incidence rate has been doubled (from 0.1 per 100,000 persons/year in 2005 to 0.2 per 100,000 persons/year).

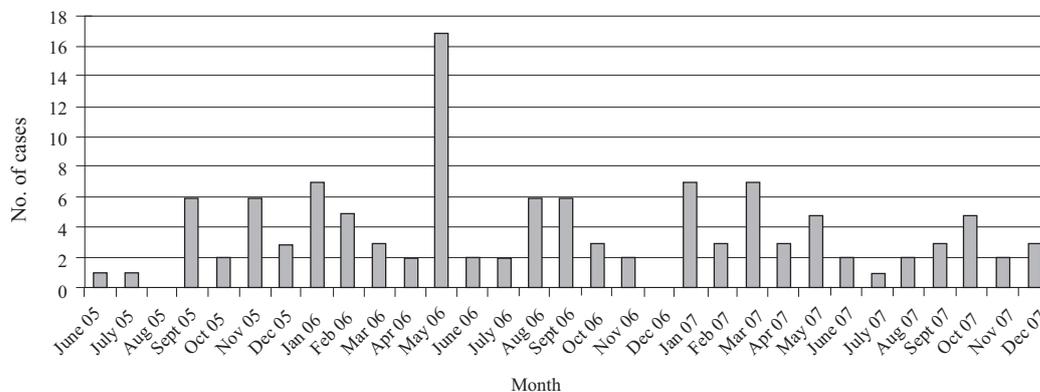


Fig. 2. Monthly distribution of reported human influenza A (H5N1) cases (June 2005 to December 2007).

Table 1. Human Influenza A (H5N1) Cases in Indonesia (July 2005 to December 2007)

Year	Cases	Fatality
2005	19	63.20%
2006	55	80.40%
2007	42	85.70%

The total number of H5N1 human cases as of December 2007 was 116, with 94 fatalities (81%). Unlike the age distribution of seasonal influenza cases, about two-thirds (65%) of the human avian influenza cases were below 25 years with a median age of 20 years; 33% were 15 years old or younger. The proportion of female and male cases was comparable (49% and 51%, respectively). The imbalance in age distribution between children and adults was statistically significant, while the proportion between males and females was not.

The case fatality proportion among children was 76%, and among adults, it was 83%; the difference was not statistically significant. However, the difference between the case fatality proportion of males (73%) and females (89%) was significant. Unrecognised, early non-specific signs and symptoms of H5N1 infection, unfamiliarity with the clinical features of H5N1 by medical providers, late clinical stage of the patients when admitted to hospitals, and rapid progression of the disease were some of the potential causes of the observed high mortality.⁴ However, with the increasing case fatality proportion, the probability of an increase in the virulence of H5N1 viruses should also be considered (Table 1).

About one-fourth (24%) of the cases occurred in 10 clusters of blood-related family members. Cases detected as a result of epidemiologic investigational activities were hospitalised just a bit earlier in their illness compared to sporadic and “index” cases (5.6 days for the subsequently reported cases detected by epidemiological investigation as compared to 5.9 days for the sporadic and “index” cases). This showed that most of the subsequently reported cases had approximately the same onset dates as the “index” cases, indicating the same exposure to a common source of infection. The days of initiating antiviral therapy, oseltamivir (Tamiflu®) among the cases detected by epidemiological investigations in clusters were also slightly earlier than among the sporadic and “index” cases (6 days as compared to 7.6 days). Although those differences were not significantly different, the case fatality proportion among the cases detected by epidemiological investigation within clusters was significantly lower (63.2%), as compared to that among the sporadic and “index” cases (84.4%). This fact might simply demonstrate the varying degrees of severity of H5N1 infection in human, i.e., the “index” cases

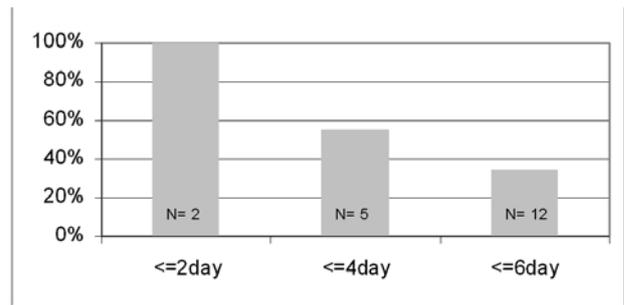


Figure 3. Days before initiation of oseltamivir

were the more severe cases, so they sought help earlier.

Despite the fact that 31 of 33 provinces in Indonesia have reported outbreaks of H5N1 in poultry, up to 2007, human cases were only reported from 12 provinces. Among them, only 46% of the cases had unmistakable history of direct contact with sick or dead poultry, such as touching and/or handling them, others (36%) had sick or dead poultry in their close vicinity, and for the rest (18%), the possible sources of infection were unclear.

Almost all of the cases (71.3%) were treated with oseltamivir, but only 2 patients received it within 48 hours after the onset of disease – both patients survived. The proportion of survivals decreased with the increasing delay to initial treatment with oseltamivir (Fig. 3). While drug resistance to amantadine was common among H5N1 influenza A virus Indonesian strain (76%) [Sedyaningsih et al., 2008, unpublished data], resistance to oseltamivir has yet to be proven.

“Mandatory” Virus Sharing Practice

The application of the International Health Regulations (IHR) 2005 is based on 2 ways of interpretation.¹⁵ The first interpretation was that IHR 2005 requires a country to share relevant biological samples as part of the duty to provide WHO with accurate and detailed public health information about all events that might constitute a public health emergency of international concern (PHEIC).¹⁶ Although IHR 2005 does not literally or specifically express the requirement for sharing of biological samples, this school of thought believes that surveillance for aetiological agents that may cause a PHEIC can only be conducted if countries share samples in a “timely and consistent” manner, without “preconditions”. This interpretation was supported by World Health Assembly (WHA) resolution adopted in May 2006 and May 2007.^{17,18} It is in accordance with this interpretation that influenza A (H5N1) specimens have been shared through the WHO’s Global Influenza Surveillance Network (GISN).¹⁹

Contrary to the first opinion, the second interpretation accepts that IHR 2005 does not require countries to share biological specimens with WHO. Public health information

and biological substances are 2 independent concepts and were actually negotiated separately; public health information strictly means knowledge and facts.¹⁵ This school of thought argues that even the WHA resolutions of 2006 and 2007 distinguished these 2 terminologies, i.e., information and relevant biological materials.^{17,18} Moreover, this interpretation strongly believes that countries have sovereign control over biological resources found within their territories, as stated in the Convention on Biological Diversity (CBD).²⁰ Hence, countries have the right and authority to decide whether to share their specimens with the WHO system or not, depending on their own judgment.

When the first influenza A (H5N1) suspect cases were reported in Indonesia in early July 2005, this country still had no national capacity to detect influenza A (H5N1) virus. However, in a relatively short time, assisted by the WHO and international aid from various developed countries, this capacity was built at the laboratory of the National Institute of Health Research and Development (NIHRD), MOH. Under the containment of Biosafety Level (BSL)-2, the detection of H5-specific viral RNA in respiratory specimens has been conducted in this laboratory by conventional and real-time reverse-transcriptase polymerase chain reaction (RT-PCR), while H5N1 antibody in sera have been tested by a modified horse red blood cell hemagglutination inhibition (HI) assay.

In adherence to the WHO policy, specimens of all positive influenza A (H5N1) human cases were sent to the WHO system, in this case – as decided by the Indonesian Ministry of Health – to the WHO Collaborating Center at the US CDC Atlanta (through the Naval Medical Research Unit 2 in Jakarta) and to the WHO H5 Reference Laboratory at the Hong Kong University (HKU). For exactly 1 year, Indonesia sent specimens from a total of 56 H5N1 positive human cases to these 2 WHO affiliated laboratories.

Incidents Leading to Indonesia's Decision to Withhold H5N1 Specimens

Since April 2006, incidents that led to Indonesia's discontentment towards the WHO system for global influenza surveillance came one after another. First, 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 notification just a couple of hours prior to the presentation, at best. Then Indonesian scientists and/or government officers were offered to be included as co-authors in papers written by international scientists who had access to Indonesian specimens sent to the WHO system, at a very late stage of the manuscript writing.

These unethical practices had actually violated the WHO

guidance for the timely sharing of influenza viruses/specimens with potential to cause human influenza pandemics released in March 2005,²¹ which stated that “*The 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*” and “*There will be no further distribution of viruses/specimens outside the network of WHO Reference Laboratories without permission from the originating country/laboratory.*”

It is important to be noted that at that time there was no document explaining what exactly “the network of WHO Reference Laboratories” were. What was generally known were only the 4 WHO Collaborating Centers and another 4 WHO H5 Reference Laboratories.²² Later on, the list was expanded to include other laboratories claimed to be essential for H5N1 vaccine development, without a clear, formal explanation of the roles and functions of each of them. All of these laboratories are in industrialised countries, and the terminology for them was changed several times, from “global research laboratories” to “essential, non-commercial research laboratories” and to “essential regulatory laboratories.”²³

Then the infamous biggest H5N1 cluster in Indonesia erupted in May 2006. Seven H5N1 confirmed cases and 1 H5N1 probable case were identified, with 7 deaths (case fatality: 88%). All 8 cases were blood relatives, with median age of 22 years (range, 1.5 to 37), and 63% were male. Clinical findings were similar to H5N1 cases in Indonesia and worldwide, and complete molecular sequence analyses of H5N1 viruses isolated from 7 cases indicated that all were clade 2 H5N1 viruses, genotype Z, and entirely of avian origin without evidence of genetic reassortment. All of these H5N1 viruses were antigenically and genetically very closely related, and similar to H5N1 viruses isolated from poultry and humans in Indonesia.²⁴

The world was obviously not ready for this. This episode was seen by many experts as a dry run for the management of an emerging pandemic virus. Some critics alleged that the responses showed how ill-prepared the international communities and affected countries were.²⁵ There were scientific debates as to whether there was already human-to-human transmission based on available epidemiological and virological data. Criticisms were addressed to Indonesia for “withholding” genetic data, and for restricting these data to a small network of researchers linked to the WHO and the US CDC Atlanta.²⁶ At that time, none of the sequence data from Indonesia viruses had been deposited in public databases.

To answer this unfair criticism, in early August 2006, the Indonesian MOH decided that all available Indonesia H5N1 virus sequence data at the US CDC Atlanta and at the HKU

should be released to the GenBank.²⁷ At the same time, in line with the increased capacity of in-country laboratories, Indonesia decided not to send specimens to the WHO system for influenza A (H5N1) case confirmation any more; human influenza A (H5N1) infection would be diagnosed and confirmed in Indonesia. However, Indonesia still agreed to share its H5N1 specimens with the WHO system – in this case to the US CDC in Atlanta – for further risk assessment, i.e., for identification and characterisation of the viruses, identification of new viruses, generation and interpretation of influenza and avian influenza associated data, and generation of seed virus for vaccine production.^{8,9}

Toward the end of 2006, a call by a journalist to the Indonesia MOH confirming news that an Australian vaccine company's plan to develop vaccine against H5N1 virus using a 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 the WHO guidance for virus sharing (March 2005), but also – as strongly argued by Indonesia – revealed the unfairness and inequities of the global system.

Disease affected countries, which are usually developing countries, provide information and share biological specimens/virus with the WHO system; then pharmaceutical industries of developed countries obtain free access to this information and specimens, produce and patent the products (diagnostics, vaccines, therapeutics or other technologies), and sell them back to the developing countries at unaffordable prices. Although it is general knowledge that this practice has been going on for a long time for other major communicable diseases – not just for avian influenza – the fear of potential pandemic influenza has magnified this gap. Moreover, in Indonesia's opinion, what has been emphasised by the current global system is merely the responsibilities of developing countries, leaving a big hole in the "rights" of these nations.

Inevitably, as of January 2007 the government of Indonesia decided to withhold its H5N1 specimens. It stated that there has been a breakdown of trust in the existing WHO GISN and a lack of benefits accruing to developing countries such as Indonesia. Indonesia urgently calls for 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. It demanded specifically, that vaccines should be available to all countries at risk of being affected at a minimal price that these countries are able to afford. Last but not least, Indonesia also calls for a full use and leverage of in-country resources, and for exchange of

global expertise in improving capabilities whenever and wherever possible.

Meanwhile, confirmed H5N1 human cases continued to be reported in Indonesia. Ever since the decision was made, there were 35 more confirmed H5N1 cases. Due to political considerations, specimens of 2 patients reported from Bali in August 2007 were sent to CDC Atlanta for risk assessment. This makes the total number of specimens not sent to the WHO system to be 33 from the remaining patients. The number of cases with a high fatality rate and the highly-publicised reluctance of Indonesia to continue to share its avian influenza viruses under the GISN system had urged the WHO to find a solution to the problem that Indonesia has emphasised.

Process to Resolve the Virus Sharing Problem

The WHO started to resolve the problem immediately after Indonesia announced its decision to withhold the H5N1 specimens. High-ranking delegates came to Indonesia to discuss the matter in February 2007. Although a Joint Statement between Indonesia and the WHO was issued as the result of the discussion, Indonesia still refused to resume the virus sharing practice.²⁸

Subsequent visits resulted in the agreement to hold a High Level Technical Meeting in Jakarta in March 2007. This WHO-sponsored meeting was followed back-to-back by a High Level Meeting initiated by Indonesia. Twenty-one countries attended the first meeting which generated a document of recommendations for responsible practices for sharing avian influenza viruses and the resulting benefits.⁷ The High Level Meeting was attended by 33 countries, and a Jakarta Declaration was promulgated.⁸ Still the situation did not change much, and hope was clearly put on the then coming WHA in May 2007.

Before the 60th WHA, the preceding Executive Board meeting in January 2007 had resulted in a recommendation on best practice for sharing influenza viruses and sequence data⁹ which overruled the WHO March 2005 guidance for virus sharing. An important point here was the stress on a country's responsibility to share its specimens/viruses without imposing "agreements or administrative procedures that may inhibit the proper functioning of the WHO GISN, including in particular the timely sharing of material and information and the achievement of the Network's objectives".²⁹

In May 2007, the WHA60.28 Resolution stipulated a series of actions to promote "transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies," while maintaining the "timely sharing of viruses and specimens." An inter-disciplinary working group (IDWG) was to be convened to review and reform

the global virus sharing system. This was really a movement forward, but the system for increasing access to vaccines and other benefits, and the non-transparency in the virus sharing system have not been changed yet. Hence, the WHA Resolution was not further ahead enough for Indonesia to resume the virus sharing practice.

The IDWG meeting in Singapore in July to August 2007 again failed to reach a consensus on a Standard Terms and Conditions (STC) for virus sharing and benefits sharing, nor a consensus on the reforms of the Terms of Reference (TOR) of the WHO Collaborating Center and WHO H5 Reference Laboratories. Attended by 22 countries representing the 6 WHO regions, the meeting succeeded in producing a Chairman's summary with a few annexed documents.¹¹ It was not quite the expected way forward, and made the work for the following International Governmental Meeting (IGM) much harder to conduct.

The IGM on *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* was conducted in November, towards the end of the uncertain year of 2007. The agenda of the meeting was too heavy for the short time allocated, and the issues discussed were too difficult to be resolved in just a formal meeting. While most of the developing countries agreed with the key principles put forward by Indonesia, most of the developed countries were in favour of maintaining the status quo and were mostly concerned to have a conclusion that required developing countries to continue to share their viruses. Hence, as had been predicted by many, the IGM could not come up with a solution. Instead, an "interim statement" was provisionally agreed to at the end of the meeting.¹⁴

Although the IGM was unable to complete its work, many developing country delegations were satisfied with the results, as the discussion and the documents were seen to have laid the foundation for a fundamental and significant change to the existing system. There was finally an admission of "a breakdown of trust" in the existing GISN system and that it does not deliver "fairness, transparency and equity." Member States "agree to take urgent action to develop fair, transparent and equitable international mechanisms on virus sharing and benefit sharing" and "agree that viruses and samples are to be shared within the WHO system, consistent with national laws, as the detailed framework for virus sharing and benefit sharing continues to be developed."¹⁴

At the end of the IGM meeting, Indonesia gave its final statement. It once again underlined that the new system cannot work without trust and that all parties should respect fairness, transparency, equity and the sovereign rights of states. To Indonesia, the practice of sharing biological specimens and viruses that abides by its national law means

the use of a Material Transfer Agreement (MTA),³⁰⁻³² a document that the WHO system has been trying to avoid so far. In the present system, the request for applying a MTA by a country contributing specimens/viruses has always been denied by WHO for "jeopardizing the timeliness" and "encumbrance" reasons, while the fact that WHO designated laboratories only transfer seed virus on the completion of a MTA (so as to protect the Intellectual Property rights of the patent holder of reverse genetics), even when sending virus back to the originating country, was not seen as a problem.

The Indonesian laws and regulations that require a MTA for any shipment of biological materials outside the country dated back to 1994 and 1995.^{30,31} Until the 81st influenza A (H5N1) human case, Indonesia had made a dispensation and had faithfully shared the specimens to the WHO system, believing that this practice was solely for the benefit of global public health. Now that the system is in the process of being reformed, Indonesia is adhering to these national regulations once again.

Conclusion

The avian influenza case in Indonesia has demonstrated once again the unresolved imbalance between the affluent "high-tech" countries and poor agriculture-based countries. Countries that are hardest hit by a disease must also bear the burden of the cost for vaccine, therapeutics and other products, while the monetary and non-monetary benefits of these products go to the manufacturers that are mostly in the industrialised countries. 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 industrialised countries' contributions are highly valued because they are human invented technology.

If the world continues to operate in this way, the discrepancies will become wider and wider. The poor will become poorer and the rich become richer. It is the responsibility of all nations to change this situation. Indonesia believes that the world must work in unity against the H5N1 virus infection and other diseases, and not taking advantage of the misery of others. The work must be conducted side by side with mutual trust, transparency and equity as global citizens and professionals, taking into consideration the elements of human dignity and solidarity.

Virus sharing is a critical part in the global effort for pandemic preparedness and global health security. Hence, the global community should continue the efforts to create a mechanism for virus access and benefit sharing that is accepted by all nations.

Acknowledgements

The writers would like to thank colleagues at the Ministry of Health and Ministry of Foreign Affairs, Indonesia; Eijkman Institute-Indonesia; provincial, district and sub-district health offices; healthcare providers at Indonesian hospitals and laboratories, for their hard work and support in controlling the avian influenza outbreak in Indonesia. We thank our international colleagues – NAMRU-2; WHO Indonesia; Hong Kong University; and CDC USA – for their contributions to our epidemiological, clinical, and laboratory investigations.

REFERENCES

- Stephenson I, Wood JM, Nicholson KG, Charlett A, Zambon MC. Detection of anti-H5 responses in human sera by HI using horse erythrocytes following MF59-adjuvanted influenza A/Duck/Singapore/97 vaccine. *Virus Res* 2004;103:91-5.
- Sedyaningsih ER, Setiawaty V, Rif'ati L, Harun S, Heriyanto B, Krisna Nur AP, et al. Karakteristik kasus-kasus flu burung di Indonesia, Juli 2005 – Mei 2006 (Characteristics of human H5N1 cases in Indonesia, July 2005 – May 2006). *Buletin Penelitian Kesehatan* 2006;34:137-46.
- Kandun IN, Wibisono H, Sedyaningsih ER, Yusharmen, Hadisoedarsuno W, Purba W, et al. Three Indonesian clusters of H5N1 virus infection in 2005. *N Engl J Med* 2006;355:2186-94.
- Sedyaningsih ER, Isfandari S, Setiawaty V, Rifati L, Harun S, Purba W, et al. Epidemiology of cases of H5N1 virus infection in Indonesia, July 2005 – June 2006. *J Infect Dis* 2007;196:522-7.
- Maines TR, Chen LM, Matsuoka Y, Chen H, Rowe T, Ortin J, et al. Lack of transmission of H5N1 avian-human reassortant influenza viruses in a ferret model. *Proc Natl Acad Sci U S A* 2006;103:12121-6.
- Siti Fadilah Supari. It's time for the world to change: in the spirit of dignity, equity, and transparency. In: Cardiyani HIS, Alex Tri Tjansono Widodo PT, editors. *Divine Hand Behind Avian Influenza*. Jakarta: Sulaksana Watinsa Indonesia, 2008.
- Indonesia to resume sharing H5N1 avian influenza virus sharing following a WHO meeting in Jakarta. 2007 Mar 27. Available at: <http://www.who.int/mediacentre/news/releases/2007/pr09/en/index.html>. Accessed 3 January 2008.
- Jakarta Declaration on responsible practices for sharing avian influenza viruses and resulting benefits. 2007 Mar 28. Available at http://www.indonesia-ottawa.org/information/detail.php?type=press_releases&id=122. Accessed 26 December 2007.
- World Health Organization. Avian and pandemic influenza: developments, response and follow-up, applications of the International Health Regulations (2005), and best practice for sharing influenza viruses and sequence data. EB120.R7, 27 January 2007.
- World Health Assembly. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits, WHA60.28, 23 May 2007.
- Briefing and Preparatory Meeting for Interdisciplinary Working Group on virus sharing, Jakarta, 9 – 11 July 2007. Document. Available at: <http://www.depkes.go.id/en/1407id.htm>. Accessed 26 December 2007.
- Interdisciplinary Working Group on pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (WHA 60.28), Geneva, 31 July – 4 August 2007. Available at: http://www.who.int/gb/pip/pdf_files/pip_igm_4-en.pdf. Accessed 26 December 2007.
- Consultative Meeting on Virus sharing and benefit sharing for pandemic influenza preparedness, Jakarta, 10-11 November 2007. Document.
- Interim statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccine and other benefits. Geneva, 21 – 23 November 2007. Available at: http://www.who.int/gb/pip/pdf_files/IGM_PIP_Intstatement-en.pdf. Accessed 26 December 2007.
- Fidler DP. Influenza virus samples, international law, and global health diplomacy. *Emerg Infect Dis* 2008;1-15 (epub).
- World Health Organization. Revision of the International Health Regulations, WHA58.3. 2005. Available at: http://www.who.int/gb/ebwha/pdf_files/wha58/wha58_3-en.pdf. Accessed 26 December 2007.
- World Health Assembly. Application of the International Health Regulations (2005). WHA59.2, 26 May 2006.
- World Health Assembly. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits, WHA60.28, 23 May 2007.
- World Health Organization. Global Influenza Surveillance Network. Available at: <http://www.who.int/csr/disease/influenza/surveillance/en>. Accessed 26 December 2007.
- Convention on Bio Diversity. Article 3. Principle. Available at: <http://www.cbd.int/articles.shtml>. Accessed 26 December 2007.
- World Health Organization. Guidance for the timely sharing of influenza viruses/specimens with potential to cause human influenza pandemics. March 2005. Available at: http://www.who.int/csr/disease/avian_influenza/guidelines/Guidance_sharing_viruses_specimens/en/index.html. Accessed 25 March 2007 (no longer exist).
- World Health Organization. List of WHO Collaborating Centres and Reference Laboratories involved in annual influenza vaccine composition recommendations & their terms of reference. Available at: <http://www.who.int/csr/disease/influenza/collabcentres/en/#ref> <http://www.who.int/csr/disease/influenza/whocccroetor2006.pdf>. Accessed 26 December 2007.
- World Health Organization. Reports by the Director-General: glossary of selected influenza-related terms to facilitate discussions in the intergovernmental meeting. A/PIP/IGM/INF.DOC./1. Geneva: WHO, 19 November 2007.
- World Health Organization. Avian influenza: Situation in Indonesia, May 23 2007. Available at: http://www.searo.who.int/en/Section10/Section1027/Section2095/Section2176_11708.htm. Accessed 26 December 2007.
- Butler D. Family tragedy spotlights flu mutations. *Nature* 2006;442:114.
- Butler D. Pandemic 'dry run' is cause for concern. *Nature* 2006;441:5545.
- Ministry of Health Republic Indonesia. Confirmation of human H5N1 infection has to be conducted in-country. Press release. March 10, 2006. Available at: <http://www.depkes.go.id/index.php?option=news&task=viewarticle&sid=2139&Itemid=2>. Accessed 26 December 2007.
- World Health Organizations. Joint statement from the Ministry of Health, Indonesia and the World Health Organization regarding the sharing of avian influenza viruses and pandemic vaccine production. Statement WHO/2, 16 Feb 2007. Available at: <http://www.who.int/mediacentre/news/statements/2007/s02/en/index.html>. Accessed 26 December 2007.
- World Health Organization. Sixtieth World Health Assembly. Provisional agenda item 12.1. Avian and Pandemic Influenza. A60/INF.DOC./2, 22 March 2007.
- Ministry of Health Republic Indonesia. National Institute of Health Research and Development. Government Regulation No 39, 1995 on Health Research and Development.
- Republic Indonesia. Law No 5, 1994 on ratification of United Nation Convention on Biological Diversity.
- Ministry of Research and Technology Republic Indonesia. Government Regulation No 41, 2006 on permission to conduct research and development activities for foreign universities, foreign research and development institution, foreign organization and foreigner.