

Indonesia, H5N1, and Global Health Diplomacy

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The World Health Organization (WHO) is mandated to be the United Nations specialized agency for health. However, in light of changing disease trends, the increased “globalization” of health, and the entry of other actors into the health arena, much of the current discourse in global health research discusses the future of the WHO and its current role in governing global health, and how this should, or can change. This paper examines the role of the WHO in global health diplomacy and the promotion of global health security by examining the Indonesian virus-sharing case. In 2007, the Indonesian government pulled out of the Global Influenza Surveillance Network (GISN), concerned that its strains of H5N1 would be used to make vaccines in the high-income countries which would then be “resold” to Indonesia at what they considered to be unaffordable prices. They were also concerned that scientists in high-income countries would be able to take out patents based on these strains, which they asserted was their sovereign property. This paper discusses to what extent the International Health Regulations (IHR) and other agreements are applicable to this case and why countries have chosen to address this issue through an intergovernmental process rather than invoking the IHR. It also questions the enforceability of international agreements and their role in promoting equity. This paper then examines why current negotiations over virus-sharing have not reached an agreement. In doing so we can use this case to ask broader question about what “effective” global health diplomacy is, how global health governance architecture could, and should change – and what should the WHO’s role in promoting global health security be, and what other actors could, and should be involved.

INTRODUCTION

Article 2a of the World Health Organization’s constitution states that the WHO is to act as the directing and coordinating authority on international health work. Although it is mandated to be the United Nations (UN) specialized agency for health, in recent years the WHO has faced criticisms of being overly politicized and a bureaucratic and static institution. Moreover, in light of changing disease trends, the increased “globalization” of health and the entry of other actors into the health arena – such as global disease partnerships and other international institutions, including the World Bank and the United Nations Children’s Fund (UNICEF) – much of the current discourse in global health research discusses the future of the WHO and its role currently in governing global health, and how this should or can change, as well as the management and governance of the WHO itself and this debate affects its global role.¹ Within this framework we must also ask how the WHO can promote global health security through global health

diplomacy - the process of making compromises and agreements in multi-actor and multi-level negotiations which is at the heart of global health governance.²

Global health security is a problematic term, used differently by different people in varying contexts. It comes out of the 1994 United Nations Development Program (UNDP) Development Report, which framed human security as freedom from fear and want, and safety from threats such as hunger, disease, repression and sudden disruptions in daily life.³ Within this, the report listed seven components of human security: economic, food, environmental, personal, community, political and health. The term can also be used to differentiate between individual (personal) health security and collective (public) health security.⁴ That is, individual health security includes equitable access to medicines, vaccines and prevention and access to health systems, whereas collective health security addresses public health risks that threaten entire group/populations and events such as pandemics, chemical spills, and nuclear accidents. Complaints over the term have risen because of the military connotations of the word “security,” and also over the United States’ use of framing AIDS as a “security issue” in the late 1990s and early 2000s, which sought to examine how AIDS was causing failed states, rather than understanding the complex relationship between poverty, general political economic conditions and AIDS. Moreover, in using this term, we ask “whose security for whom?” That is, by framing health concerns as “security issues” in the international relations sense, countries risk becoming protectionist, rather than focusing on achieving *global* health security for the world.

This paper utilizes the case study of Indonesia and virus-sharing to highlight some of the questions - and possible solutions – within these global governance, diplomacy, and health security debates. In 2007, Indonesia pulled out of the Global Influenza Surveillance Network (GISN), concerned that its strains of H5N1 (avian influenza) would be used to make vaccines in high-income countries which would then be “resold” to Indonesia at what they considered to be unaffordable prices. The Indonesian government was also concerned that scientists in high-income countries would be able to take out patents based in part on these strains. The sharing of virus samples is necessary because it allows researchers to track the evolution and spread of resistance, to evaluate the risk of a pandemic and allows for the development of vaccines.⁵ As Indonesia had more confirmed H5N1 human cases and deaths of any other country, its withdrawal from the network was particularly concerning, and posed a threat to global health security.⁶

This paper outlines the Indonesian case and reviews international agreements, especially the IHR, and the use of World Health Assembly (WHA) resolutions and the Convention on Biological Diversity, with which the case is concerned. It then examines the limitations and ambiguities of these agreements and discusses why countries have chosen to work through the issue via an intergovernmental process rather than by invoking international law. This paper concludes that, although “hard” laws are very useful in many instances, in their current state they do not address the concerns of Indonesia, nor are necessarily the most effective method of addressing these issues or Indonesia’s reluctance to share virus samples. Further, this paper argues that instead we should examine

why current negotiations over virus-sharing have not been resolved, and concentrate on examining global health diplomacy and how this can be more effective. Although this case demonstrates a gap in the current global health governance architecture, it also presents an opportunity for reform and asking questions such as how the WHO can re-define itself as a forum for global health diplomacy and what other actors can and should be involved and in what roles, which is addressed in the conclusion.

THE INDONESIAN CASE

The Global Influenza Surveillance Network is not a binding network or international regulation, but is a structure within global influenza governance.⁷ It has operated for nearly 60 years, and functions by participating countries sending samples to one of four collaborating centers (UK, US, Japan, Australia) where those samples are analyzed. The WHO then decides which strains pose the most risk and decisions are made on how to proceed with vaccine production accordingly.⁸

2003-2006

Highly pathogenic H5N1 influenza A was first identified amongst poultry in Indonesia in December 2003. In 2005, Indonesia reported the first human H5N1 case and by the end of 2007, it had the largest number of cases (116) and a case fatality rate of over 80 percent.⁹ Although the outbreak was concentrated in Indonesia, it was not limited to the country and there were fears of a widespread pandemic.

2007

In January 2007, Indonesia ceased to share virus samples with the GISN, after having learnt that an Australian pharmaceutical company had developed a vaccine based on an Indonesian strain without their knowledge or consent.¹⁰ Indonesia argued that the current methods of vaccine production and distribution were neither equitable nor transparent. That is, current global capacity for vaccine production does not meet demand and most of those vaccinated were from high-income countries,¹¹ although the greater burden of disease is in lower-income countries. That Indonesian samples would be used by pharmaceutical companies to create vaccines that were unlikely to be available to Indonesia was deemed “unfair” by Indonesian Minister of Health Siti Fadilah Supari,¹² and she questioned the incentives that countries like Indonesia have to continue sharing their samples. Specifically, countries that are hardest hit by a disease must also bear the brunt of the cost for vaccines and treatment, while the benefits of these products are enjoyed by pharmaceutical companies, mainly in higher income countries. In this sense, poor countries have no bargaining position.¹³

Another concern of the Indonesian government was transparency within the virus-sharing system. For example, there were no reference documents

explaining exactly the roles and function of not only the four WHO collaborating centers, but also other laboratories involved in the vaccine development.¹⁴ The situation was further exacerbated by the WHO's acknowledgement that patents had been sought on modified versions of H5N1 samples shared via the GISN within the consent of their countries of origin.¹⁵ The Indonesians also invoked the Convention on Biological Diversity (1992), which mandates that countries share in the benefits if their genetic resources are utilized by others.¹⁶

In March 2007, following back-to-back meetings between the WHO and Indonesia in Jakarta, Indonesia announced it would resume the sharing of virus samples. This was achieved in part by promises by the WHO to help increase global vaccine production capabilities and suggestions by WHO representatives to explore short-term responses such as national stockpiling of vaccine and influenza drugs, and guarantees that if industry were to set aside a percentage of the vaccine, the WHO would purchase these.¹⁷ The WHO also agreed to revise the current Terms of Reference for WHO laboratories, which would outline agreed uses of the virus samples, including their provision to pharmaceutical companies.¹⁸ Long-term suggestions included the bulk transfer of vaccines and technology from current manufactures to pharmaceutical industries in low and middle-income countries.¹⁹ Indeed in April 2007 the WHO convened a meeting to assess the feasibility of vaccine stockpiling and increasing pharmaceutical production. Also in April 2007 the WHO awarded a total of \$18 million to Brazil, India, Indonesia, Mexico, Thailand, and Vietnam to develop their own vaccine manufacturing capability.²⁰ This meeting was also followed by a High Level Meeting of 33 countries and sponsored by the Indonesians at which the Jakarta Declaration set out the need for transparent, fair and equitable virus-sharing.

After the March 2007 meeting the GISN did receive three samples.²¹ In May 2007, a news piece in *Lancet Infectious Disease* featured the header, "Dispute resolved over sharing avian influenza virus samples."²² However, the dispute was far from over. Throughout the remainder of 2007, Indonesia remained reluctant to share virus samples²³ and in the past year (2009) Indonesia has not shared any samples with the GISN, including those from H1N1 (swine flu). Even with regard to releasing notifications of avian influenza, they have tended to only let out information in batches at certain times of the year. Indonesia furthered their cause at the World Health Assembly in May 2007 of that same year. Resolution WHA60.28, agreement upon which was only reached through intense negotiations, called for action to promote the "transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies" whilst simultaneously maintaining the "timely sharing of viruses and specimens." Out of this Resolution an interdisciplinary group was also created to address issues in the global virus-sharing network, such as transparency and clear terms of references with WHO laboratories. The Resolution also requested the Director-General to address the issues of vaccine access and increasing manufacturing production in low and middle-income countries. However, Indonesia did not feel that this Resolution adequately addressed the issues of access to vaccines and the sharing of other benefits or the issue of transparency in the virus-sharing system and thus remained hesitant to share sample.²⁴

In July-August 2007 the interdisciplinary working group (IDWG) met in Singapore but did not resolve the issue, failing to reach consensus on a Standard Terms and Conditions for virus-sharing, as well as on the reforms of the Terms of Reference for the WHO laboratories.²⁵ Following the failed IDWG meeting, in November 2007 the International Governmental Meeting (IGM) on “Pandemic Influenza Preparedness: Sharing of Influenza Viruses and access to Vaccines and Other Benefits” met in Geneva. The statement that came out the meeting was not agreed upon by all participating member states, but it provisionally acknowledged the breakdown of trust in the system. It also noted the need for fair, transparent, equitable, and effective international mechanisms to ensure access to H5N1 vaccines, and the WHO was tasked to establish a tracking system for virus samples and an oversight mechanism in the form of an independent advisory group for monitoring and further developing the system.

It was in this meeting that Indonesia pushed for the use of a Standard Material Transfer Agreement (SMTA) for each sample sent out-of-country, and insisted that they would not send samples overseas without an SMTA. In this, they would specify that the sample be used only for diagnostic purposes and any commercial use of the sample (i.e. vaccine production) would require the permission of the country where the sample originated.

2008

In Spring of 2008, Indonesia also banned NAMRU, a U.S. Navy Medical unit in Jakarta that had analyzed biological samples. The unit had been in operation for decades but its memorandum of understanding had expired in 2006 and efforts to renew it were unsuccessful, due to disagreements over SMTAs. Indeed the US was, and continues to be, one of the countries in opposition to SMTAs, claiming that the terms of agreements in terms of benefits-sharing desired by Indonesia and other states would decrease incentives for pharmaceuticals to create new technologies in vaccine production.²⁶

The open-ended working group met in April 2008 in Geneva, where member states discussed the WHO’s beta version of a virus-tracking system as well virus-stockpiling. It was decided that these issues, as well as benefit sharing, would be further discussed at the next IGM in November.

By May 2008, Indonesia was still refusing to share virus-samples, but announced it would share genetic sequences of its virus through the newly-launched Global Initiative on Sharing Avian Influenza Data (GISAID). On GISAID’s internet based platform, scientists can upload their influenza sequences as well as epidemiological and clinical data to what is known as its EpiFlu™ database. The initiative also encourages collaboration among countries as well as scientists. The platform is designed and maintained by scientists, for scientists from various disciplines of the influenza research, including veterinary and human virology, bioinformatics, epidemiology, immunology, and clinical analysis, etc. Although GISAID’s data is publicly accessible, it does not fall under the definition of Public Domain, as GISAID does not remove nor waive any preexisting rights where such rights exist. That is, scientists who sign up agree to consult with whoever uploaded the original sample before any publications or

intellectual property-rights agreements are made using the sample. This system introduces the transparency that was lacking in the GISN.²⁷

Although Supari supported the GISAID, the overall issue of virus-sharing was still unresolved. Additionally, one drawback of GISAID is that it is a sharing of influenza data only, not actual samples and there are limitations to predicting viral evolution based only on sequence data. At the 61st World Health Assembly later in May 2008, virus-sharing was again on the agenda and member states expressed the need for a quick resolution and hope that the issues would be fully resolved at the next IGM.

At the same time, virus-sharing via the GISAID system was also hampered. Within four months of its launch, GISAID had become the world's largest and most comprehensive database (AP 2008). However, the WHO was reportedly withholding funds earmarked to support GISAID, and was in the process of developing their own database and tracking system. The dispute was over \$450,000 from the US Centers for Disease Control and Prevention. According to the US Department of Health and Human Services and GISAID, this money was earmarked for GISAID. According to the WHO, the money had been earmarked for a database, but because of the amount involved the WHO was required to put out an open tender. According to the WHO's David Heymann "for the first time in decades, developing countries are looking at the [WHO] with mistrust and officials cannot afford to be partial to any group," and that this was a direct order from the Director-General Margaret Chan. Yet, many flu scientists and governmental officials felt that this situation actually did nothing more than to add to mistrust of the WHO.²⁸

In November and December 2008, the 3rd IGM and the open-ended working group met to establish a framework for the sharing of both virus-samples and benefits. Although successful in agreeing upon some wording in the terms of reference and other documents, progress remained slow.

2009

Prior to the 62nd World Health Assembly in May, the 4th IGM convened. This meeting ended with a consensus on most of the above mentioned issues, and the IGM submitted a draft framework "Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits" to the WHA for consideration. However the issues of data-sharing between laboratories, intellectual property rights on viruses and remained unresolved.²⁹ Specifically with regard to the SMTA, two questions remained unresolved:

- (1) If the recipient shares with someone who is not a signatory to the agreement, is the agreement binding with this third party?
- (2) If they use the materials for purposes it was not intended for, is there any legal recourse?³⁰

From this draft framework, the WHA adopted WHA62.10 on Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits. This called upon the Director-General to facilitate a transparent

process to finalize the Framework, including the Standard Material Transfer Agreement. From this, the Director-General held a 2-day consultation with member states later in 2009. However, disagreement remains regarding the SMTA, benefit-sharing and intellectual property rights.

2010

In the run-up to the 2010 World Health Assembly, Indonesia maintains its calls for increased equity and transparency in the virus-sharing scheme. There is also a 3-day open-ended member state meeting scheduled before the 63rd WHA in May 2010 to discuss the outstanding issues and virus-sharing is the first item on the agenda for Committee A, followed by the IHR and intellectual property issues. Although progress has certainly been made in that the draft framework has been largely agreed upon, the situation continues as a stalemate with the aforementioned outstanding issues and many countries are currently negotiating bilateral agreements with regard to material transfer agreements. Indonesia has also taken steps to establish a WHO influenza collaborating center in which they could analyze their own samples without sending them out-of-country.³¹

INTERNATIONAL AGREEMENTS

Sovereignty is the underlying principle of international law, and this concept maintains that a state has authority and control over the people, resources, and functions within its borders. Within international law, states are prohibited from intervening in each other's domestic affairs, but limits on sovereignty arise when states agree to be bound by international law.³² It has been suggested that the International Health Regulations, in combination with several World Health Assembly resolutions, could have been used to force Indonesia to share its virus samples, and their use was discussed by the WHO Secretariat and by member states. Additionally, Indonesia claimed that its virus samples were its sovereign property, invoking the Convention on Biological Diversity (CBD). Here, this paper will briefly review the IHR, World Health Assembly Resolutions, and the CBD. Although this paper argues that a focus on international law is far too narrow when discussing the overall issues, it is necessary to understand their limitations and why they were not explicitly invoked in order to then examine the gaps in global health governance and possible solutions, which will be discussed further in subsequent sections.

The International Health Regulations

The International Health Regulations (IHR) is an international legal instrument, binding on its 194 signatory countries, including all WHO Member States. The aim of the IHR is to facilitate global communication and cooperation for early detection and containment of public health emergencies of international concern (PHEIC).³³ The IHR obliges signatories to notify the WHO when these PHEIC occur. The International Health Regulations have their origins in the 19th Century International Sanitary Regulations, which were revised into the

International Health Regulations in 1969. The IHR 1969 included provisions for six diseases, which were later reduced to three (cholera, yellow fever and plague) to reflect changing disease patterns and the eradication of smallpox. Against the backdrop of globalization (specifically increased trade and travel), it was recognized that the IHR needed to be updated. A revision process began in the 1990s and was pushed forward by the SARS outbreak in 2003,³⁴ as China's subterfuge in reporting SARS demonstrated a need to take into consideration unofficial reports of public health. These revisions culminated in the revised IHR, which went into force in 2007. Certainly, the 1969 IHR were lauded as the first health-related binding treaty, but specific limitations were addressed in the revisions, such that currently:

- The scope is not limited to any specific disease, but covers “public health emergencies of international concern.”
- Includes obligations of the signatory states to develop minimum public health capacities.
- The WHO may take into consideration unofficial reports of public health events; they are no longer required to rely fully on “official” sources; however, these unofficial sources are to be verified by official accounts.
- That said, they require the establishment of National and WHO IHR Contact Points to facilitate urgent communication.
- The procedures for the Director General of the WHO to determine a PHEIC are clarified.
- The human rights of persons and travelers are protected.
- The revisions also update technical and regulatory functions, such as requirements for international ports.³⁵

It is important to note that the GISN was not organized under treaty law, and the most relevant international law to virus-sharing would be the IHR. The 1969 IHR did not at all include influenza, nor did it require the sharing of biological samples.³⁶ Although H5N1, as a PHEIC, is covered in the revised IHR, the sharing of biological samples is not explicitly required. However, under international law, a state must refrain from acting against a treaty's object and purpose. Article 2 of the revised IHR states:

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

One could interpret this to mean that the withholding of virus-samples is against the aims of the IHR, and thus in violation of the treaty.³⁷ At a technical briefing at the World Health Assembly in 2007, Director-General Margaret Chan stated that “countries that did not share avian influenza virus would fail the IHR.”³⁸ Under a risk assessment framework, one can also argue that the IHR

require virus-sharing, as risk assessment cannot be conducted without the sharing of biological samples.

World Health Assembly Resolutions

The WHO is both an entity and a forum of, and for member states. That is, the supreme decision body of the WHO is the World Health Assembly. The WHA meets annually in May to determine the program of work and to approve the budget. Each member state sends a delegation of no more than three delegates who are most technically qualified in health, preferably representing the national health administration. Although technically the principle of “one state, one vote” governs the WHA, the majority of decisions are the WHA are reached by consensus in advance of the WHA. These decisions often come in the form of resolutions. Most of actions resulting from resolutions are then carried out by the WHO Secretariat, the WHO’s administrative and technical organ.³⁹ In other words, WHA resolutions are soft laws. They are usually binding on the Secretariat, and prescribe the work it must carry out, but typically “urge” member states to do something, and are not binding on the member states.

In 2006 the WHA adopted Resolution WHA59.2, which called upon member states to comply immediately, on a voluntary basis, with the provision of the revised IHR considered relevant to the risk posed by avian influenza. The point, which will be discussed below, is that although adopted in 2005, the revised IHR were not scheduled to go into effect until 2007. The resolution urged member states to “disseminate to the WHO collaborating centers information and relevant biological materials related to highly pathogenic avian influenza and other novel influenza strains in a timely and consistent manner.”

This resolution, when used in conjunction with the IHR, supports the interpretation that sharing biological samples is part of a country’s requirement to provide accurate and detailed public health information under the IHR. However, WHA Resolutions are non-binding on member states, and can only “urge” them to act.

Convention on Biological Diversity

In making its case, Indonesia invoked the Convention on Biological Diversity (CBD). The United Nations Environment Program (UNEP) began work on the CBD in the late 1980s, recognizing the importance of maintaining biological diversity, as well as the threats faced by various species and ecosystems as a result of human activities. The Convention also addressed concerns that resources in lower and middle income countries were being exploited by richer countries. The treaty was finalized in 1992 and went into force in 1993, with the objective of:

the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer

of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.⁴⁰

The Convention gives countries sovereign control over the biological resources found within their borders and according to Indonesia, this includes virus-samples.⁴¹ According to Article 2 of the treaty, biological resources include “genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use or value for humanity,” and Article 15 states “the authority to determine access to genetic resources rests with the national governments,” and that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources and that access “shall be on mutually agreed terms.”⁴²

Using this treaty, Indonesia claimed that virus-samples collected in its territory were its property and that under the treaty’s provisions, consent should be obtained before other parties use its samples, and that Indonesia should also share in the benefits produced by those samples, such as vaccines. Moreover, this claim is reflected in the WHA60.28, whose preamble recognizes the “sovereign right of States over their biological resources.”⁴³ However, as with the use of the IHR, there are ambiguities in the applicability of the CBD to virus-sharing, which will be discussed below.

ISSUES IN APPLYING IHR AND INTERNATIONAL AGREEMENTS TO THIS CASE

In the case of Indonesia, issues both specific to this case and those that are more general concerns within of global health governance and diplomacy and international law can be seen. The standard critique of international law, particularly health law, is that it is unenforceable. Another issue is that of ambiguities. Although some law is very specific, in many cases international law can be ambiguous and member states have an interest in keeping it ambiguous so that they have room for manoeuvre.⁴⁴

Specifically to this case, IHR is ambiguous in the matter of virus sample-sharing. The agreement does not expressly require the sharing of biological samples, but a good faith interpretation of the agreement, backed by WHA59.2 does. Also, WHA60.28, the resolution negotiated at the 2007 WHA, called not only for transparency and equity in virus-sharing, but also the “timely sharing of viruses and specimens.”⁴⁵

However, the scope of “public health information” is ill defined in the IHR and a secondary interpretation is that it includes surveillance data and other facts, but not biological samples.⁴⁶ Moreover, Article 6.2, on notification, states that member states should communicate to the WHO “sufficiently detailed public health information...including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed.” Yet, it does not list “biological samples.”⁴⁷

Another contentious point is that the timing of the IHR going into force coincided with Indonesia’s case, such that it was unclear whether or not their use was valid. Although negotiated in 2005, the treaty had no binding force until it

officially entered into force in June 2007. Under international law, states are meant to uphold the aims and objectives of a treaty once they have expressed their consent to be bound by it, pending its entry into force. Additionally, member states had until December 2006 to bring reservations to the treaty; Indonesia submitted none.⁴⁸

Even if the validity of the IHR in this situation was unquestioned, the question of enforceability is again raised. As is, the WHO remains unable to act without the consent of its member states. Although member states chose to take the issue out of the IHR framework and into inter-governmental negotiations in part due to the questionable applicability of the IHR to this situation, there were other reasons as well which will be discussed below. In this sense, the IHR can only be enforced by the will of the member states. Additionally, the IHR only contains a weak dispute resolution mechanism, a point to which this paper will return in the sections below. Moreover, if the IHR were to be invoked, it is unclear what this would look like, and how its enforcement could occur without violating the principle of sovereignty. Specifically, the WHO is not a supranational body, and has no authority to violate this principle, although it can be argued that the use of unofficial notifications in the IHR is creeping into this area.

Writing after the SARS outbreak, Kickbusch suggested exploring sanctions by the UN Security Council, the WTO and the IMF for countries not adhering to global health transparency and their obligations under IHR.⁴⁹ Garrett and Fidler also put out the idea of utilizing the UN Security Council, writing that “continued failure to break the stalemate may encourage countries threatened by the withholding of virus-samples to pursue high-stakes strategies to break the deadlock, perhaps by seeking United Nations Security Council intervention on the grounds that failure to share.”⁵⁰ Their point is that if virus-sharing were framed as a security issue, it could theoretically be put to the Security Council. When Kickbusch suggested Security Council action in response to non-transparency, she was addressing China’s refusal to allow the WHO to visit the Guangdong province, where SARS emerged, or to visit military hospitals where SARS patients were hidden.⁵¹ However, one of Indonesia’s arguments was that the WHO virus-sharing system was not transparent at all. In this sense, could the WHO or individual member states be taken to the Security Council because they were impeding global health security through the inequities and lack of transparency within the GISN? Regardless, it is unlikely this would be put before the Security Council, simply because of the Council’s remit. There have been only six Security Council resolutions on health, two of which involved Palestine at the time of Israel’s founding and the four since 1997 have dealt with health in conflict areas. Additionally, in light of China’s sensitivity towards using infectious disease as cause to interfere with state sovereignty, its presence on the Security Council makes it highly unlikely that the Council would intervene.

The other issue called into question was the validity of applying the Convention on Biological Diversity to this case, as the Indonesians did. Their interpretation was that the Convention gives countries sovereign control over the biological resources found within their borders.⁵² The other point is that in Article 57, the IHR explicitly lays out its relationship to other practices of

international law, writing that the provisions of the IHR “shall not affect the rights and obligations of any State Party deriving from other international agreements.” Indonesia used this to support its claims under the CBD.⁵³ However, Fidler argues that the CBD was not intended to be applied to pathogenic viruses, and this application is contrary to the Convention’s purpose, which was to assist states in conserving and maintaining biological diversity.⁵⁴ Stevenson and Cooper take the stance that although the CBD does not explicitly cover virus-sharing, Indonesia’s use of it is within the spirit of the convention because it highlights existing structural inequality, in this case how vaccines are created and who benefits from their production (financially and physically), especially at times of global crises.⁵⁵ Another dispute point is that claims of sovereignty over pathological organisms are problematic. For example, if a person with seasonal influenza travelled to another country and was exposed to H5N1 and the strains mutated to combine a new virus, it is unclear to whom that virus belongs. Sovereignty is also particularly difficult with avian influenza, which is carried by fowl that migrate thousands of miles and across many national borders.

DISCUSSION

Why an intergovernmental process?

As discussed above, there are clear issues of both applicability and enforceability in using international agreements in this case, but there are other reasons why the IHR were not invoked and countries chose to use an intergovernmental process. Firstly, the use of the IHR was discussed at the WHO Secretariat, but as the IHR had just been negotiated and revised, both the Secretariat and member states were loathe for their first use to be one of punishing another member state.

Moreover, Indonesia made the world clearly aware of these issues of transparency and benefits-sharing. It has been questioned why, if Indonesia had the support of a significant number of member states, it was the only one to cease sharing virus samples. Firstly, Indonesia was a special case. Although H5N1 was clearly not contained to Indonesia, it had the highest number of human cases and fatalities and the country was thrust into the center stage; this focus on Indonesia, combined with the government and political situation at the time contributed to Indonesia’s decision, as did the revelation that a pharmaceutical company was using its samples without its knowledge. In terms of the other member states, in spite of the equity and transparency issues, it was in the best interest of the other member states to share their virus-samples. Because Indonesia had brought the issue to the agenda, there was not a need for other member states to actually pull out. However, this paper suggests that not invoking the IHR was also a way of showing solidarity for Indonesia.

Finally, the key failing in Indonesia’s case is one of trust. As Sedyaningsih and colleagues point out, some of the virus-sharing practices of the WHO actually violated its own guidelines. These have since been changed in light of the current situation, but at the time they were released in 2005 they stated:

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 the WHO Reference Laboratories without the permission from the originating country/laboratory.”⁵⁶

In addition to discovering an Australian pharmaceutical company was to produce a vaccine based on its virus, throughout 2006, results from laboratory analyses on Indonesian strains were presented at international meetings without the prior consent or notification to the Indonesian government or scientists. At very late stages of the writing process, Indonesian scientists and governmental officials were offered to be included as co-authors in papers written by international scientists based on Indonesian strains obtained via the WHO system.⁵⁷ At the time, there was no explanation of the role and functions of WHO-affiliated laboratories or exactly why the “Reference laboratories” were expanded beyond the four WHO Collaborating Centers and the four WHO H5 Reference Laboratories.⁵⁸

Some recognition was received by the statement from the 1st IGM in November which acknowledged the breakdown of trust in the system, but this begs another question of enforceability: how can the WHO promote and enforce equity, and does its reassurance have weight? Arguably, trust is the WHO’s greatest asset. It is an institution with a long history and has had many successes, having eradicated smallpox and effectively handled SARS. Even where it has been less successful, such as realizing the goals of the Alma-Ata declaration and malaria eradication, its intentions have always been good. Yet, in this situation it did not act transparently, or in the best interests of poorer nations. This trust can certainly be rebuilt over time, but it will take a significant effort and changes, some of which are discussed below.

Solutions

The next question to ask is why the negotiations have not been resolved after three years, and what are possible solutions? According to an Indonesian official, “the most important reform in the WHO level is the reform of the virus sharing and benefit sharing mechanism in such a way that make it a fair, transparent, and equitable mechanism.” This section examines some of the specific outstanding issues and possible solutions, and in the following section more general options for improving the environment for global health diplomacy based on this case will be examined.

The first issue regards transparency on data-sharing and standard material transfer agreements (SMTA). Although GISN has operated for decades with few problems, the situation has changed since the 1950s, and there is an increasing demand and need for documents, agreements, and the tracking of biological samples, in part because of this breakdown of trust. Although the

intergovernmental working group has been creating mechanisms for increased transparency, there needs to be continued communication amongst the WHO Secretariat and member states, and this trust needs to be rebuilt over time. Conversely, on the other side of the argument are countries, such as the United States, which oppose the SMTAs. This is an interesting point, as the US is in favour of SMTAs with regards to issues of bioterrorism, which suggests that there may be other reasons behind their reluctance for SMTAs.

A second point is reform of international law. Although it has already been demonstrated above, current law is inapplicable to the situation, there is scope for change. It was decided by the 61st WHA that the revised IHR should be reviewed within five years of their implementation, and they are currently under review in relation to H1N1 and other public health events. The preliminary findings of the review are to be presented to the 63rd WHA in May 2010, with a final report in May 2011.⁵⁹ Because the IHR was only recently revised and that revision was a 12 year process, member states are unlikely to call to negotiate a further revision. However, issues of equity and virus-sharing may be discussed in this review and the IHR can be amended at the will of the member states. Another issue with the IHR is the lack of a strong dispute mechanism. Article 56 suggests that if two member states cannot solve a dispute on their own, they can put it to the Director-General of the WHO. In the event of a dispute between WHO and one or more state parties concerning the interpretation or application of these Regulations, the matter is to be submitted to the World Health Assembly. Again, this section could be clarified and in the final section of this paper, other options regarding the development of a dispute mechanism for issues both inside of and outside of international law will be examined.

There have also been moves by some countries to add pathological entities to the CBD. However, this could be damaging, as are bilateral processes. That is, viruses ignore state borders and samples do not typically differ radically amongst neighbors. If the CBD were to cover viruses, neighboring countries could theoretically get into a bidding war with pharmaceutical companies over their samples. Ultimately, this is in no one's interest. Rather, sharing samples and ensuring access to benefits is in everyone's interest. Moreover, the issue of establishing sovereignty over a pathogen – whose virus is it? - remains. Within the CBD framework there are also negotiations for an International Regime on Access and Benefits sharing, which would also further the promotion of benefits sharing and access as laid out in Articles 15 and 8 of the Convention. Again, depending on how the Convention is interpreted in the future, this Regime could have an impact on health.

Instead, the focus should be on benefit-sharing. Public health crises lead to change and, as Fidler points out, WHA60.28 does not itself produce equitable virus-sharing, but establishes a WHO-based process for moving global health diplomacy in this area and is a “general blueprint” for building new global governance mechanism, particularly with regard to equitable virus-sharing.⁶⁰ As laid out by the IGM, sharing viruses contributes to increased global health security through appropriate risk assessment and response. Benefits also include the “access to and transfer of technology for influenza vaccine development and production, strengthened national capacity related to influenza preparedness and

response, improved risk management through establishment of stockpiles and/or provision of: pharmaceuticals, personal protective equipment and other supplies necessary during the response to an outbreak; non-commercial diagnostic tests and materials; influenza vaccines and ancillary supplies.” Although it is not collectively useful for individual states to “sell” their vaccines to pharmaceutical companies, it would be collectively useful for the WHO to negotiate on their behalf. The practice of the WHO providing biological samples to pharmaceutical companies freely to pharmaceutical companies has occurred for decades. The Indonesians brought this to the forefront by pointing out the inequities of this. It is not suggested that the WHO start selling biological samples, only that the WHO serve a “global health diplomacy” role in negotiating benefits. For example, in the IGM the point was put forward that the recipient of materials (i.e. a vaccine producer) should agree in writing to contribute to the Global Influenza Vaccine Fund (GIVF).

Other venues to which we can turn for guidance include activities on intellectual property right and genetic resources by the World Intellectual Property Organization’s intergovernmental committee who work closely with UNEP and the Food and Agricultural Organization (FAO). The FAO has also produced the International Treaty on Plant Genetic Resources for Food and Agriculture contains provisions for material-transfer agreements, benefits sharing and other concerns brought up by Indonesia. A full discussion of IP rights is outside the scope of this paper, but ensuring a balance between commercial interests and benefits-sharing must be addressed if situations such as this are to be resolved.

Another benefit is empowerment though strengthening capacity. The 2005 IHR revisions also gave countries five years in which to fulfil obligations in terms of implementing WHO recommended measure, and developing capacity for the detection, reporting, assessment of, and response to PHEICs. However, as Kamradt-Scott notes, lower and middle-income countries face challenges in implementing these reforms and other measures that higher income countries are able to enact.⁶¹ Enabling countries to develop not only the surveillance and response capacities as laid out in the IHR, but also to create and manufacture pharmaceuticals promotes global health security. Moreover, if lower and middle-income countries were to be empowered in this way, and if the WHO were to follow-through on its promises with regards to increasing vaccine production and increasing other capacities, then lower and middle-income countries may be more likely to concede or compromise within the negotiations.

Finally, the overarching problem is that the global vaccine production capacity is woefully inadequate and production capacity is concentrated in higher income countries. Current global capacity for season influenza vaccine production is estimated at only 500-900 million doses, although in a pandemic situation up to three times as much could be produced, using monovalent, rather than trivalent vaccines.⁶² However, even in a pandemic situation, we still take into the account the need to continue producing seasonal influenza vaccines. WHO has taken steps to increase capacity – for example, in 2007 they awarded a total of \$18 million to Brazil, India, Indonesia, Mexico, Thailand, and Vietnam to develop their vaccine manufacturing capability.⁶³ In 2008 the Organization also

announced plans to stockpile H5N1 vaccines and out of the virus-sharing situation have come efforts to create a policy framework for vaccine allocation and use.⁶⁴ However this situation clearly needs to be fully addressed.

PROMOTING GLOBAL HEALTH SECURITY THROUGH REFORM

Again, the case of Indonesia can be used to ask broader questions about what “effective” global health diplomacy is, how should and could global health governance architecture change – and what should the WHO’s role in promoting global health security be. In the wake of SARS, Ilona Kickbusch wrote that the outbreak presented a “wake-up call for a strong global health policy,” and the virus-sharing situation does as well. Again with SARS, one of the main issues was China’s unwillingness to cooperate, and although the global health world has not been completely reformed in light of SARS, from it the IHR was significantly revised to take into account the need to accept reporting from unofficial sources. Yet, global health security will be created only if the issues of equity, benefit-sharing and transparency are addressed, and the wider question now is what modes of governance can promote global health security and address future global health crises.

WHO level reform

In her address to the 55th World Health Assembly in 2002, Dr. Gro Harlem Brundtland, then Director-General, stated:

in a world filled with complex health problems, WHO cannot solve them alone. Governments cannot solve them alone. Nongovernmental organizations, the private sector and Foundations cannot solve them alone. Only through new partnerships can we make a difference... Whether we like it or not, we are depending on the partners, the resources and the energy necessary for at least a 30-fold scale up in effort – to bridge the gap and achieve health for all...I should add that in every joint venture we seek to define what each partner can bring to the relationship. We identify where potential conflicts of interest may limit certain types of interaction. We aim to play to each others’ comparative advantages....

The point here is for the WHO to redefine its role and competencies and to create various types of partnership where applicable. Lee writes of the on-going tension within the WHO between a focus on disease and health, and a focus on the broader determinants of health. Traditionally the WHO has focused on the former but increasingly, as we recognize the impact of social, trade, economic, and foreign policies on health the WHO has moved towards the latter.⁶⁵ However, no one body could feasibly be competent in all of these areas. Additionally, with regular budget of \$1 billion⁶⁶ the WHO is limited in what it can do, even within health.⁶⁷ Although this initially seems a large amount, one must

remember this is the same amount of money donated to health causes by the Bill and Melinda Gates foundation each year, a considerable amount of which is channelled through the WHO as extra-budgetary funds. The WHO is mandated to be the coordinating authority on all international health work. In considering reform, the WHO must think about how to ensure that it is coordinating effectively, and who can do which tasks most effectively. The WHO should also increase its role in global health diplomacy, for example, negotiating with pharmaceutical companies when it transfers virus-samples.

Finally, it is outside the remit of this paper to discuss all types of partnership, but one sector to examine is the role of civil society and non-profit organizations. For example, in the IHR revisions “unofficial sources” may now inform the WHO of PHEIC. In the virus-sharing situation, one can also look at the role of GISAID. Although the WHO Secretariat was hesitant toward it, in the 2009 draft framework for virus-sharing, member states expressed their desire for the WHO laboratories to submit their genetic sequences to publicly accessible databases, and recognized GISAID in their final report of the World Health Assembly.

Governance outside the WHO

Returning to the lack of a dispute mechanism, in which part of the issue is a loss of trust in the WHO Secretariat, and the other aspect is that negotiations have not been resolved after three years, one must ask how the WHO fits into wider global governance mechanisms, and what other bodies could and should be involved. The WHO is both an entity and a forum for member states. Simply put, the WHO Secretariat carries out the work as directed by the member states, mainly through World Health Assembly resolutions. In the virus-sharing example, trust within the WHO Secretariat was broken and Indonesia took issue with both the Secretariat and with individual member states, particularly those opposing SMTAs, notably the United States. If two countries are in a trade dispute, they can bring it to the World Trade Organization (WTO). However, in this case, there is no WTO-esque dispute mechanism, the WHO is not designed to be a “WTO for health,” and part of the dispute is with the actions of the WHO Secretariat itself. A further point is that even if a decision were reached at the WHO level, it would be unenforceable which creates a disincentive for reaching a mutual agreement.

In more general terms, this is similar to what would happen if two UN bodies were in a dispute that could not be resolved by their respective Director-Generals or individuals within their secretariats. As discussed above, after SARS Kickbusch suggested exploring the possibility of UN Security Council sanctions against member states not adhering to IHR obligations.⁶⁸ Garrett and Fidler also ask “what if,” if states were to put this before the Security Council. Although the virus-sharing issue can be framed as a “security issue,” it is very unlikely to be dealt with by the Security Council and most global health issues are simply not within its present remit.

Taking this debate outside the context of the UN system, the G8, G20 and regional groups may fill some of the gaps within global health governance. Health

has featured significantly on the G8 agenda, though their financing of new health initiatives, such as the Global Fund to Fight HIV/AIDS, TB, and malaria. Additionally, while the G8 itself has not been directly involved in virus-sharing negotiations, G8 representatives have been present at the Inter-governmental meetings on virus-sharing.

However, the G20 is a far more inclusive entity (and includes Indonesia and other countries that are directly affected by equitable access to medicines). In her blog, Oxford's Devi Sridhar asks if the G20 is simply a short-term crisis arrangement focussed narrowly on economic issues, or if it could be relevant to other issues areas, such as health, and specifically asks what role they could play in virus-sharing. If the G20 were to widen its discussion beyond economic issues, it could serve as a forum for addressing health issues.⁶⁹ As Sridhar points out, the advantage of cross-cutting groupings – such as the G8 or what the G20 could be, is that they have the potential to facilitate coordination amongst sectors, such as health, finance, trade and agriculture – all of which impact upon health. Sridhar also hastens to add that we must not neglect the important role that regional groups, such as Union of South American Nations (UNASUL) or Community of Portuguese Speaking National (CPLP) have had in health, and she further cites the role that ACMEC (Cambodia, Lao PDR, Myanmar, Thailand and Vietnam) have had in the virus-sharing negotiations.⁷⁰ Conversely, health professionals need to understand how health fits into the wider international relations and political context. For example, although this paper focuses on virus-sharing, at the same time there are overall issues with “Western” countries exploiting poor countries for resources such as mineral, oil and gas. In Indonesia specifically, there have been deadly protests at the Freeport mine in Papua province, owned by the US company Freeport-McMoRan Copper & Gold Inc.

As evidenced in the SARS case, which contributed to the reform of the IHR, crises can lead to change. Questions of improving global health governance are not new, but at the moment there are more questions than answers. This paper certainly cannot be so arrogant as to suggest reforms; it can only agree with Nick Drager and others in that the most sensible course is for WHO member states call for the next WHO Commission to create recommendations of how global health governance architecture could, and should be redesigned. In addition, member states could call for this commission to consider the role the WHO Secretariat should play in reform, and what methods and modes of collaboration and cooperation should exist amongst it, civil society, the private sector, other UN agencies, and regional and global institutions, such as the G8 and G20, the WTO, and the International Monetary Fund and World Bank. Within this framework, proposals for Committee C of the World Health Assembly should also be considered and debated. Committee C could be a first step in creating a mechanism for coordinating global health efforts amongst these various actors, and through it the WHO could serve as a coordination body for global health programs and formally link member states and non-governmental health actors.⁷¹ In this sense, we can think of the health sector as a large corporation in need of restructuring. The questions of who has competency in what areas, who should do what, who should outsource various functions to whom and who should coordinate – and where can these individual “divisions” –

i.e. institutions - turn for assistance and under which circumstances must be asked. Finally, although this is certainly a post-Westphalian world, what aspects of sovereignty individual countries are willing to give up within this global health governance architecture must also be considered.

CONCLUSIONS

The WHO is moving away from a body to offer only technical assistance, and toward a focus on the broader determinants of health. A secondary role of the WHO is to ensure that health stays on the wider foreign policy agenda. As the virus-sharing negotiations have continued for three years without resolution, some of the urgency and political will has been lost. This is not to say it is off the health agenda, only that it is less of a priority in wider political agendas. Effective global health diplomacy includes not only negotiation and dispute resolution, but also linking health to other sectors. Within current and future global health negotiations it is important that the lessons of equity, transparency and access illuminated by the virus-sharing case not be forgotten, and to take away lessons from the Indonesian case when considering reforms in the global health governance environment.

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