

The 2011 Pandemic Influenza Preparedness Framework: global health secured or a missed opportunity?

ABSTRACT

In early 2007 the Indonesian government announced that it would cease sharing H5N1 influenza virus samples with the World Health Organization (WHO)'s Global Influenza Surveillance Network. At the heart of the government's complaint was the fact that samples were being passed by the WHO to pharmaceutical companies that developed, and patented, influenza vaccines that the Indonesian authorities could not purchase. The decision gained widespread support among advocates of greater equity of access to medicines, and in response, the WHO established an intergovernmental process to agree a framework for influenza virus-sharing. The process officially concluded in April 2011 and a new Pandemic Influenza Preparedness Framework (PIPF) was agreed at the 64th World Health Assembly in May 2011. This paper investigates the events that prompted the re-examination of a technical cooperation system that has provided effective global health security on influenza for sixty years, and evaluates the framework that has now been agreed. Drawing the distinction between functional and moral-political benefits, the paper argues that PIPF more accurately represents a diplomatic standoff – one that has now been effectively sidelined with the passage of the agreement – rather than genuine reform. In fact, the PIPF papers over fundamental disagreements regarding authority in global health governance, the relationship between the WHO and governments, and the role of private industry. The paper concludes by examining an alternative mechanism that would arguably better address the inherent tensions between national and collective interests, and achieve the functional and moral-political benefits that the negotiations set out to achieve.

Keywords: global health security; influenza; virus-sharing; Indonesia; H5N1

Word length: 8,413 words including references (target 9,000 words as per author guidelines)
With abstract (max 250 words) 8,662 words

Introduction

Since 2001, attempts by the World Health Organisation (WHO) to engage more actively with foreign policy have been framed in terms of “global health security”, with a particular focus on the spread of infectious diseases (McInnes and Lee 2005). As the WHO Director-General Margaret Chan observed in 2007, “better security calls for global solidarity” which, she argued, can only be achieved through greater “diplomacy, cooperation, transparency and preparedness” (WHO 2007a, vii). As she penned these words, Chan was likely reflecting on Indonesia’s announcement weeks earlier that it would cease sharing samples of the highly lethal H5N1 influenza virus with WHO’s Global Influenza Surveillance Network (GISN), claiming a breakdown of “mutual trust” (Sedyaningsih, Istandari, Soendoro and Supari 2008). For over 60 years, the GISN served as the sole mechanism for advising governments on the content of seasonal influenza vaccines, and for alerting the world to the emergence of influenza viruses with pandemic potential. Indonesia’s actions immediately cast doubt over the technical cooperation framework, highlighting the anomaly between the expectation that all countries should provide virus samples, and the lack of access for most countries to the vaccines produced from these samples.

Indonesia’s decision, and Minister of Health Dr Siti Fadilah Supari who announced it, were immediately and widely condemned by policy-makers, public health practitioners and scholars for potentially putting the world’s health at risk (Garrett and Fidler, 2007; Holbrooke and Garrett, 2008). However, among advocates of access to medicines, Supari became a *cause celebre* for daring to challenge a system seen as highly inequitable (Anon 2008a; Belford 2008). In response, the WHO announced the creation of a global stockpile of influenza vaccines that LMICs could access based on demonstrated need, and initiated intergovernmental negotiations to resolve the disagreement. In April 2011, the negotiations concluded with a new set of technical cooperation guidelines – the Pandemic Influenza Preparedness Framework (PIPF).

This paper examines the diplomatic negotiations surrounding influenza virus sharing as an example of the core tensions characterising multilateralism and emerging forms of global health governance (GHG). The paper begins by briefly exploring the background to the negotiations, the main challenges faced during the negotiations, and the structural factors that

currently inhibit equitable access to influenza vaccines. It then assesses the extent to which the PIPF resolves those challenges by distinguishing between functional and moral-political benefits of the negotiation process and resultant framework (Touval 2010). It is argued that the intent behind the multilateral negotiations was generally agreed to be two-fold: to develop a new technical cooperation agreement and to re-legitimize the authority of the WHO's GISN. For those countries that supported Indonesia's actions, the intended functional benefit of the negotiations was to reform the GISN's processes and systems to facilitate equitable access to influenza vaccines and other benefits. Only in this way would the second moral-political benefit of re-legitimizing the WHO-coordinated network be achieved. Yet while most countries agreed the existing technical cooperation system did need reform, disagreements persisted over the extent of those reforms and in particular, over the WHO's authority versus that of governments, and the role of private industry within pandemic influenza preparedness. As a result, for those countries that were largely supportive of the former system, the functional benefit of the negotiations was to ensure technical cooperation in virus sharing resumed as soon as possible. Once these practices resumed, the moral-political benefit of re-legitimizing the WHO's GISN (based on inclusiveness) would also be achieved. As will be argued below, however, ultimately the PIPF has failed on both counts to fully achieve either set of objectives. For while a new agreement has been reached, because of the time taken, fundamental disagreements over the nature of authority within GHG, and the inescapable need for compromise to achieve consensus, neither sets of objectives were able to be fully met. Furthermore, the PIPF has failed to adequately tackle the embedded structural inequalities, namely, the existing market-based political economy surrounding influenza vaccine production and procurement. The paper then concludes by putting forward an alternative mechanism which, we argue, would better address the inherent tensions between national and collective interests, enhance global health security, and realize both the functional and moral-political benefits that the virus sharing negotiations set out to achieve: namely, expanding the WHO's *Global Pandemic Influenza Action Plan to increase Vaccine Supply (GAP)*.

Background to the Virus-Sharing Negotiations

Influenza is, arguably, the most democratic of viruses, with the potential for some strains in today's globalized world to affect entire populations regardless of age, gender, socioeconomic status or geographical location (Jones 2010; Kilbourne 2006). The ease and speed with which influenza viruses can spread and, in the case of lethal strains such as H5N1 their potential to cause high numbers of infections and deaths, presents a significant risk to the international community. It is this risk that led to the formation of the GISN 60 years ago under the auspices of WHO's Global Influenza Programme (GIP). The network operates by receiving influenza virus samples from participating countries via their National Influenza Centres (NICs) that are then forwarded to one of six designated WHO Collaborating Centres (WHO CCs). The virus samples are then isolated to identify which strains of the virus are circulating and where at a given time. Augmenting GISN's work is FluNet, an internet-based program operated by WHO that links together the NICs and WHO CCs in a virtual worldwide network to ensure the rapid exchange of global surveillance data. The information generated by these two networks is then passed to pharmaceutical manufacturers that use the data to develop seasonal influenza vaccines and, in the event a novel strain emerges against which there is limited or no human immunity, a new pandemic-specific vaccine.

In this context, GISN has been central to contemporary international efforts to mitigate the perennial risk posed by seasonal influenza, and the periodic risk from pandemic influenza. In 1997, for example, GISN was placed on high alert and assisted Hong Kong's administration contain the outbreak of H5N1 that infected 18 people and caused the death of six individuals. In 2003, the network was again placed on high alert following the identification of H5N1 for a second time in Hong Kong (WHO 2010b); and following the virus' progressive geographical spread within and beyond Asia since 2004, GISN has served as the primary vehicle coordinating international technical cooperation to control the virus. Similarly in April 2009, the network proved critical in coordinating the international response to the H1N1 pandemic, conducting regular systematic surveillance to detect the extent of antiviral drug resistance (WHO 2010c).

After operating effectively for decades, GISN was thrown into disorder in 2007 following the Indonesian government's announcement that it would cease sharing H5N1 virus samples with

the WHO. The government claimed a breakdown of “mutual trust” citing several incidents that included:

- laboratory analyses that utilized H5N1 viruses from Indonesia that were presented at international meetings in April 2006 without prior consent from Indonesian authorities;
- the announcement of what appeared to be evidence of human-to-human transmission of the H5N1 virus following a cluster outbreak in May 2006 prior to Indonesian verification; and
- the decision by an Australian pharmaceutical manufacturer to produce an influenza vaccine based on an Indonesian H5N1 virus sample provided to the WHO without the Indonesian government’s authorization (Sedyaningsih, et al 2008).

In 2006, Health Minister Supari had also attempted to purchase a supply of the antiviral medication *Tamiflu* for a national stockpile, but had failed “because the medicine had been purchased by developed countries for stockpiling” (Supari 2008, 5). The WHO had specifically recommended countries purchase large quantities of this drug, as it was believed that it might assist in treating patients infected with H5N1 until an effective vaccine could be developed (WHO 2007b). Reflecting the widespread concern that an H5N1-inspired pandemic was imminent (Fidler 2008; Collin and de Radiguès 2009), many high-income countries entered into advance purchase agreements (APAs) with Roche – the sole manufacturer of *Tamiflu* – and various vaccine manufacturers, to secure access to supplies of antivirals and pandemic-specific influenza vaccines. This increased demand combined with limited global production capacity meant that by 2006 when the Indonesian President authorized a diversion of budgetary funds to develop a national stockpile of influenza drugs, Indonesia confronted a queue. As Supari went on to note in her monograph *It’s Time for The World to Change*, the “sweeping out of the Tamiflu stock by developed countries that had no cases of the disease...really made a deep wound in my heart” (Supari 2008, 5). This combination of events prompted the health minister to then announce in December 2006 that her government would cease sharing H5N1 virus samples with the WHO in an attempt to force a fundamental restructuring of existing governance mechanisms including GISN – a position that found immediate support amongst many LMICs that confronted the same constraints.

In an attempt to resolve the subsequent impasse, WHO announced the immediate creation of a global stockpile of pandemic influenza vaccines that all low-income countries could access based on demonstrated need. In addition, a series of meetings were held in 2007 between WHO and the Indonesian government in an attempt to address the latter's concerns ahead of formal negotiations for an international agreement on virus-sharing (Fedson and Dunnill 2007). Following the passage of World Health Assembly resolution WHA60.28 in May 2007, representatives from 109 countries attended the *Intergovernmental Meeting on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits* (the 'PIP-IGM'), alongside representatives from various international and non-governmental organizations. Given that the outcome of the negotiations would have a bearing on pharmaceutical companies, a delegation from the International Federation of Pharmaceutical Manufacturers and Associations was also invited to attend (WHO 2007c). In passing WHA60.28, member states requested that the PIP-IGM address two core issues: (a) the inequitable access to influenza vaccines by all countries *in the event of a pandemic*, and (b) how benefits derived from the provision of virus samples could be better distributed to facilitate equitable access to vaccines. Importantly, it was originally envisaged that the best way to accomplish these objectives would be to develop a framework that would apply to all influenza virus-sharing activities. As the WHA resolution noted, this was because the sharing of all influenza virus specimens was considered essential to the "assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medications" (WHO 2007). Accordingly, this principle was reflected in the first draft text that arose from the 2007 PIP-IGM meetings that advocated,

Timely, transparent, accountable, and [free] [mandatory] international sharing of clinical specimens and *H5N1 and other viruses from human sources which may cause influenza pandemics [to (GISN members who are in good standing in the operation of the network) WHO mechanisms which have been in good standing in respect of practices and processes for assessment of pandemic risk,]* is critical for the assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, [and] surveillance for resistance to antiviral medications [*and other public*

health orientated research]. (italics original, bracketed text indicates no consensus, WHO 2008a, 32).

Noting the existing constraints to access, the WHO's member states also requested the Secretariat to "mobilize financial, technical and other appropriate support from Member States, vaccine manufacturers, development banks, charitable organizations, private donors and others, in order to implement mechanisms that increase the equitable sharing of benefits" (WHO 2007). The benefits the resolution referred to were listed, and included:

- the capacity to locally manufacture influenza vaccines;
- to enhance local research and surveillance capacity, including appropriate staff training, along with the ability to identify and characterize H5 and other influenza viruses;
- financing mechanisms to ensure timely and affordable procurement of pandemic-specific vaccines for those countries in need; and
- access to an international stockpile of vaccines for H5N1 and other influenza viruses with pandemic potential (WHO 2007).

Accordingly, this principle was again reflected in the draft text, with the delegates at the PIP-IGM agreeing,

The international benefit sharing mechanism must be transparent, and aimed at ensuring fair and equitable sharing *of*, and access to, and distribution of benefits *based on public health need*, especially developing countries, in a timely manner, and particularly *but not limited to* during public health emergencies of international concern (italics original, WHO 2008a, 33).

Nonetheless, by mid-2008, member states engaged in the negotiations had agreed to scale back the intended scope of the agreement, noting explicitly that the agreement "applies to H5N1 and other influenza viruses with human pandemic potential. It does not apply to seasonal influenza viruses" (WHO 2008b, 5). This change in focus was significant in that it narrowed considerably the scope for benefits sharing and intellectual property (IP) rights, effectively negating the ability to achieve wide-ranging reforms. As such, while a general consensus emerged that the system should more effectively address the needs of LMICs (especially in obtaining access to vaccines), disagreement persisted over the extent of the reforms needed to

achieve this and over three critical issues in particular: (a) how biological materials were transferred between GISN members and external parties such as pharmaceutical manufacturers; (b) how benefits could be shared amongst interested parties; and (c) how IP rights should be balanced with affordable access.

Without consensus on the above issues, the PIP-IGM was officially disbanded in May 2009. For many involved, the outcome was not particularly surprising. At various junctures throughout the negotiations Supari had instructed her staff that, in her view, a diplomatic deadlock was preferable to compromising (Supari 2008, 74-82). In recognition, however, of the fact that diplomacy needed to continue (particularly in light of the H1N1 influenza outbreak that emerged in April 2009) WHO Member States authorized the establishment of the *Pandemic Influenza Preparedness Open-Ended Working Group* (the 'PIP-OEWG') at the 62nd World Health Assembly (WHA) in May 2009. In preparation for its first meeting, the WHO Director-General convened a special meeting of interested parties in October 2009 in an attempt to resolve some of the outstanding concerns. Yet despite the Director-General putting forward a new draft text, and the replacement of Indonesia's health minister (Anjani 2009), consensus remained elusive. Further discussions were postponed until the PIP-OEWG was then formally convened in May of the following year.

The first PIP-OEWG meeting was conducted over two days in May 2010 attended by delegations from 79 Member States, along with representatives from the African Union and European Union. Demonstrating the extent to which disagreement persisted four different proposals were advanced regarding the structure and purpose of the arrangements that would guide virus sharing (otherwise known as 'Standard Material Transfer Agreements' or SMTAs). The only apparent point of consensus that did emerge was that the majority of delegations agreed the need for multiple approaches and tools to address the current challenges (WHO 2010d). The meeting concluded by calling on the WHO Secretariat to conduct further studies on topics such as the amount of laboratory, surveillance, and vaccine production capacity-building currently underway; new strategies for enhancing access, affordability, and deployment of influenza-related pharmaceuticals; and sustainable financing. A second OEWG meeting was then held in December 2010 to monitor progress, ahead of the third and final meeting in April

2011 where the Secretariat submitted its findings and recommendations, and the new framework was agreed.

The structural hurdles to equitable access to influenza vaccines

Prior to evaluating the outcome of the virus sharing negotiations and the particular benefits and drawbacks of the new PIPF agreement, it is important to take into account a number of existing structural, or systemic-level factors that currently inhibit equitable access to influenza vaccines. These structural factors primarily derive from, and are centred around, the current market-based political economy of influenza vaccine production and consumption. The first structural hurdle concerns the present lack of demand for seasonal influenza vaccines in most countries that has, in turn, limited overall global vaccine production capacity.

For decades the only major purchasers of seasonal influenza vaccines have generally been high-income countries led by the United States, the United Kingdom, Australia, Japan, France, and Canada (Lee and Fidler 2007). Many LMICs have traditionally been reluctant to purchase such medicines simply because of other more pressing health needs that must take priority in resource-constrained environments. Thus, even though the disease can affect any population, limited availability, high cost, and ongoing resource constraints meant that vaccine manufacturers developed a skewed preference towards high-income countries as their primary customers. As profit-making enterprises though, pharmaceutical companies will generally produce goods for which there is sufficient demand at a price that exceeds production costs. Economic theory holds that, all things being equal, when demand increases, more producers enter the market and the corresponding increase in supply leads to lower prices. Where this occurs, supply and demand equalizes. While there is scarcity of supply, however, high demand can result temporarily in higher prices.

From an economic theory perspective it could be argued that the pre-2005 balance between supply of and demand for seasonal influenza vaccines was in equilibrium. LMICs were not demanding the vaccines and thus supply was accordingly low. Importantly though, seasonal and pandemic influenza vaccine production are inexorably linked as the same manufacturing plants that produce vaccines for seasonal influenza also produce a pandemic-specific version if, and

when, it is required. Given that high-income countries have conventionally been the primary customers (and via government investment, frequently also the subsidizers) of seasonal influenza vaccines, pharmaceutical companies have tended to locate their infrastructure and expertise in those same locales. Correspondingly, by 2006 the bulk of the world's manufacturing capacity for influenza vaccines was focused in only nine industrialized countries (Kieny et al, 2006).

[Insert Table 1 here]

Added to this, a second structural hurdle relates to the advance purchase agreements (APAs) that a number of high-income countries have agreed with pharmaceutical manufacturers in order to secure access to influenza medications. These agreements, which primarily arose between late 2003 and 2006 in direct response to the perceived risk and anxiety that a pandemic was imminent, served to limit the availability and supply of influenza-related drugs even further. Even taking into account the projected increases in influenza vaccine production (see below), under these arrangements it is unlikely that many LMICs would gain access to a new pandemic-specific vaccine until the demands of those countries with APAs had been met, and well after a pandemic had commenced. If, therefore, access is to be made more equitable either through the introduction of measures such as tiered pricing, or population-based or geographical distribution quotas, these APAs need to be annulled, re-negotiated, or mitigated in some way. This is not likely to be easy given that the rationale for APAs derives from the tendency for governments, when confronted with a potential existential threat, to look to protect their domestic population in the first instance.

A third structural limitation arises from the fact that the existing vaccine production system relies upon a wide range of public and private actors, including fully or partially government-owned and operated laboratories, private research facilities, and pharmaceutical companies with varying levels of government and private sector investment. Not surprisingly, the interests and priorities of these groups of actors differ considerably – just one of many factors that delayed the emergence of the new agreement. Notwithstanding the new initiatives launched

under the WHO's *Global Pandemic Influenza Action Plan to increase Vaccine Supply* (see below), according to 2009 data, 34 companies across 19 countries comprise the world's entire influenza vaccine manufacturing capacity (WHO 2009c). Even as of 2011, the total annual capacity for trivalent seasonal influenza vaccine production is estimated at 876 million doses, with the seven largest companies (all located in industrialized countries) producing 64 per cent of available stock (Collin and de Radiguès 2009; WHO 2011b). Whereas in 2006 the industry market was valued at US\$2.2 billion, it is projected to more than double by 2016 due to investment by high-income countries concerned about the threat of pandemic influenza (DataMonitor Healthcare 2007; Collin and de Radiguès 2009). This expansion will not occur, however, without considerable additional investment from the private sector, either in the form of new standalone initiatives or public-private partnerships.

The new pandemic influenza preparedness framework

Within this context, a number of concerned governments met together in a series of talks that extended over more than four years to arrive at a new framework to enhance pandemic preparedness. Importantly, as noted above, the scope of the negotiations was narrowed to develop an agreement that would facilitate the rapid sharing of influenza virus samples with human pandemic potential, and ensure greater access to vaccines and associated benefits (WHO 2011a). To achieve these stated objectives, the PIPF agreement identifies principles, norms, governance mechanisms and oversight arrangements that all members of the WHO's global influenza surveillance and response system (GISRS) and other allied institutions are expected to comply with. The document outlines, for example, a series of recommendations relating to the sharing of influenza viruses with pandemic potential, diagnostic equipment, laboratory and disease surveillance capacity building, medication stockpiling, technology transfers, and tiered pricing, amongst others.

It must be said that one of the core benefits of the new framework is that it places a range of obligations on those pharmaceutical companies that utilize GISRS information and virus samples. For example, under the terms of the agreement manufacturers that are members of the GISRS must now contribute 50% of the network's overall running costs. Although details are

not provided on how costs are to be shared between companies (i.e. ability-to-pay, % of overall profits, etc), this new arrangement transforms what was previously a publicly-financed network (supported by Japan, Australia, United States and the United Kingdom) into a new public-private partnership. Companies that are not members of GISRS (and therefore exempt from contributing to operating costs) are required to agree to a package of measures designed to promote improved access to medicines and diagnostics for low-income countries in exchange for access to data and samples.

Aside though from a number of additional stipulations on the WHO Director-General relating to his/her duties in facilitating access to vaccines and antivirals and implementing certain oversight mechanisms and arrangements, the remainder of the agreement is non-binding. Member states and pharmaceutical companies are only encouraged to adhere to certain behaviours or principles (as evidenced by repeated reference to “should” throughout the text of the agreement as opposed to “shall” or “must”). There is no explicit obligation, for instance, on governments to require or compel pharmaceutical manufacturers (which may be government-owned and/or operated) to transfer vaccine technology to low-income countries, to ensure a certain percentage of stock is available for purchase by LMICs, or to implement tiered pricing arrangements for vaccines and/or antivirals. Nor, for example, is there any legal requirement to assist governments in enhancing laboratory, surveillance, or regulatory capacity. This lack of obligation on member states is not unusual and reflects the long-standing inviolability of state sovereignty. The absence of significant assurances from private industry though is a slightly unusual (albeit an expected) outcome – one that arguably reflects the fact that the previous technical cooperation system was entirely voluntary and the potential risk that pharmaceutical manufacturers may choose to exit the industry if too many barriers or obligations were imposed upon them.

It is in this regard that for low-income countries the intended functional benefit of the PIPF negotiations has not been achieved. Indeed, given the repeated references to “should” as opposed to “shall”, the PIPF agreement is inherently weak. LMICs have been able to obtain a small number of concessions from those pharmaceutical manufacturers that are not official members of the GISRS, in the form of commitments to provide 10% of medicines and

diagnostics at more affordable prices. Beyond this, however, low-income countries have gained very little in the way of improved access to vaccines or technical assistance, or even commitments for improved access in the future. The PIPF has thus only imposed minimal changes on the existing market-based political economy surrounding influenza vaccine production and procurement. Correspondingly, serious questions have to be asked whether the outcome of negotiations, the PIPF, has in any way repaired the damaged legitimacy of the WHO's GISN.

Equally, given that it took over four years to resolve the diplomatic impasse while also prompting LMICs to seek additional assurances to protect genetic resources in an alternative forum, it is difficult to accept the intended functional benefit of the PIPF negotiations was achieved for those countries that were largely content with the former cooperation arrangements either. One of the primary motivations for initiating the talks was to ensure Indonesia's swift resumption in sharing H5N1 influenza samples. The fact that the Indonesian authorities refused to do so, even once the talks commenced, meant that the negotiations failed to mitigate the (so far unrealized) risk to the international community from a H5N1 influenza pandemic. Moreover, the negotiations encouraged LMICs to strengthen the protection of genetic resources through developing a new, more prescriptive protocol under the Convention of Biological Diversity (CBD) – the Nagoya Protocol (UNEP 2011). Of course, now that the negotiations have concluded and Indonesia has resumed sharing samples, GISN may be viewed as having clawed back a measure of legitimacy. Even in this though, questions will persist over whether these negotiations have resulted in a fairer and more equitable system, and accordingly, both the network's legitimacy and the associated moral-political benefit of the PIPF agreement also remains in some doubt.

In fact, to some extent several new risks have emerged that the PIPF has now been agreed. For example, given that a new framework has been endorsed there is now the very distinct possibility that the issue of equitable access to influenza vaccines will be supplanted by other, more pressing international matters. If this were to occur, particularly given the PIPF does little to address the embedded structural market-based inequalities that prevent equitable access to vaccines such as increasing global production capacity or mitigating the APAs, it could be

argued that global health security has actually been hampered by a diplomatic “success”. Added to this, the imposition of what effectively equates to user-fees for pharmaceutical companies that access GISRS data and samples, either through directly funding the network or via commitments to provide at least 10% of vaccines and diagnostics at reduced prices, raises the possibility that some manufacturers will exit what has traditionally been a low-profit industry (Sheridan 2005). In the remainder of this paper, we explore an alternative approach – one that would more adequately address both the functional and moral-political benefits that the virus sharing negotiations were intended to accomplish, while also more fully addressing the structural hurdles currently inhibiting equitable access to pandemic influenza vaccines.

An alternative solution to the PIPF to enhancing equity in access

Somewhat ironically, the *Global Pandemic Influenza Action Plan to increase Vaccine Supply* (GAP) was launched by the WHO in September 2006 – some four months prior to Indonesia’s decision to cease sharing samples of the H5N1 virus (WHO 2006). The purpose of the GAP is essentially to increase overall global manufacturing capacity of influenza vaccines thereby providing a larger proportion of the world’s population access to these essential medicines in the event of a pandemic. To launch the program, the US Department of Health and Human Services, UK Department of Health, Public Health Agency of Canada, the Japanese International Cooperation Agency, Asian Development Bank (ADB), Bill & Melinda Gates Foundation, and United Nation Children’s Fund (UNICEF) provided the initial funding (Jadhav, et al 2010). The GAP outlines a three-fold agenda for action:

- (a) to increase the demand for seasonal vaccines in order to stimulate the market to increase supply;
- (b) to increase global production capacity for pandemic vaccines; and
- (c) to encourage new research and development in vaccine-related technology (WHO 2006).

The central premise of the GAP is recognition that production capacities for seasonal and pandemic influenza are inherently linked. By seeking to increase seasonal vaccine demand, the GAP aims to encourage more pharmaceutical manufacturers to enter the market. In theory, this will not only improve access by increasing the existing supply of vaccines, it will also serve to lower prices, thus making vaccines more affordable to LMICs. Likewise, by supporting new research and development in vaccine technology, the GAP aims to encourage innovation in such areas as reducing the delay between identifying the virus strain and producing a vaccine, decreasing the amount of vaccine required to confer immunity, and/or the development of new vaccine delivery methods. The intended by-products of this activity is to increase overall global production capacity that can be utilized in the event of a pandemic while also providing countries with the means to procure affordable vaccines.

Perhaps most importantly, the principles that the GAP promotes have initially attracted strong support from LMICs such as India, Brazil, Thailand and Mexico, as well as support from high-income countries such as the United States, the United Kingdom, France and Singapore (WHO 2009b). One of the more significant initiatives launched under the program has been a technology transfer project aimed at strengthening influenza vaccine production in LMICs. The project was initially launched by the WHO's Initiative for Vaccine Research (IVR) in February 2007 with seed funding provided by the US Department of Health and Human Services, the Japanese government (via UNICEF), and the ADB. Some 13 proposals were received in the first round of applications and, following a peer-review process six were successfully funded (WHO 2009b). A further five proposals were funded from the second tranche of applications submitted in late 2008 with the result that by 2010 a total 11 countries including Iran, Brazil, Indonesia, India, Egypt, Mexico, South Korea, Thailand, Viet Nam, Serbia, and Romania, had initiated projects (WHO 2010d).

A second key achievement under the GAP has been to secure access for LMICs to live attenuated influenza vaccines (LAIV) technology. This is a notable achievement in that production yields for influenza vaccines are reportedly much higher using LAIV technology as less vaccine is required to confer immunity. Moreover, the technique is less labor-intensive (WHO 2006), and so the overall cost per dose is approximately one-tenth that of producing the

more common inactivated vaccines (Kieny, et al 2006). Until recently, the pharmaceutical company Nobilon held the rights to this technology and LAIV production was restricted to a few million doses per year (WHO 2009b; Kieny, et al 2006). The agreement struck under the WHO's GAP thus offers considerable promise for LMICs seeking access to more affordable influenza vaccines, and a small number of countries have already begun developing this technology under the IVR technology transfer project (Jadhav, et al 2010).

The third significant achievement under the WHO's GAP has been the establishment of a global stockpile of H5N1 influenza vaccines. In November 2007, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommended that the Organization establish a stockpile of 150 million doses of H5N1 vaccines, and ancillary equipment such as needles and syringes (WHO 2009b). Of the total stockpile, SAGE recommended that 50 million doses be designated for rapid deployment in the event of an outbreak of human H5N1 cases, with the remaining 100 million doses to be distributed to LMICs in the event of a pandemic. To date, three pharmaceutical manufacturers have provided pledges to donate vaccines, including GlaxoSmithKline (50 million doses) Sanofi Pasteur (60 million doses) and Omnivest (100 million doses) (WHO 2009b).

Beyond these three main achievements, however, the WHO action plan has attracted only passing political interest, evidenced by the fact that it has failed to garner sustainable financing in order to support its expansion and ongoing operation (WHO 2010d). The H5N1 vaccine stockpile, for instance, is not physically in existence as yet. Rather, feasibility studies are still being conducted over whether a physical stockpile should be created or whether a virtual stockpile with pledges from pharmaceutical companies to deliver their nominated number of doses is considered sufficient (WHO 2009b). Likewise, the IVR technology transfer project has reached the limit of existing funding arrangements and, without further investment, it is unlikely that other LMICs will be able to access funds to build and/or enhance their local manufacturing capacity. Unless additional funds are made available for a third, and potentially fourth, tranche of international grants, it is highly unlikely that global production will meet the demand for vaccines created by a pandemic.

To that end, while the new PIPF agreement has now been endorsed, we contend that the international community would be better served overall by now re-focusing its attention on ensuring appropriate levels of funding to expand the WHO's GAP. For example, the further expansion of local vaccine production capacity via an enlarged IVR technology transfer project largely circumvents high-income countries' stranglehold on existing vaccine stocks via APAs and the existing inequity that accompanies greater purchasing power. In supporting LMICs' building, and/or expansion, of local manufacturing capacity, new avenues for securing access to affordable vaccines would be created at the same time as expanding overall global capacity. These new sources of supply reduce the imperative for governments to enter into contractual arrangements with established manufacturers to secure access to vaccines. Moreover, it reduces the need to try and renegotiate, or cancel, those APAs already in force in order to make the current environment more equitable. In this regard, countries' self-interest in seeking to protect their respective populations via APAs is not adversely affected, nor do governments have to be persuaded to moderate their access to vaccines (thereby increasing their own insecurity) in the face of the ongoing existential threat from the H5N1 virus. In short, supporting LMICs to build and/or strengthen local vaccine production capacity through additional investment in the IVR technology transfer project is a "win-win" scenario for the global community.

Further, in encouraging and supporting low-income countries to develop local pharmaceutical manufacturing facilities, these same governments will also be encouraged to strengthen their national scientific laboratory capacity. This positive by-product has the potential to yield yet further advantages in that, once a research and manufacturing baseline has been established, companies based in low-income settings may eventually come to rival pharmaceutical companies based in high-income countries, generating their own IP through research and innovation. Admittedly, this type of benefit requires a long-term commitment and investment, but the potential nonetheless exists to level the playing field between LMICs and their high-income country counterparts.

Finally, expanding the GAP with a focus on new R&D serves to navigate a way through the complex arrangements of the contemporary vaccine production system. As noted earlier, there

exists a strong need for private sector participation and the GAP establishes a broad framework for encouraging collaboration between state and market actors. Until broader questions surrounding the protection of IP and innovation rights are resolved, and the related debates surrounding access to medicines and the role of private actors in public health are satisfactorily addressed, a politically strategic approach would be to focus on those areas of technical cooperation where consensus already exists and can be built upon. As noted earlier, considerable support exists for the GAP among low and high-income countries and the further expansion of the program is largely contingent upon securing additional funds for implementation.

It is also in this regard that expanding the GAP would achieve both the functional and moral-political benefits that the virus sharing multilateral process was originally intended to achieve. As argued above, further enlargement of the GAP would expand global production capacity through establishing a series of formal agreements and funding arrangements to foster local pharmaceutical manufacturing capacity in low-income country settings. This in turn would facilitate more equitable access to pandemic influenza vaccines as well as amassing a number of related benefits such as improved indigenous scientific capacity, research and development, and IP. Were this to occur, it would likely negate many of the concerns low-income countries held (and possibly still hold) over the potential exploitation of virus samples and the lack of benefits that accrue to them via technical cooperation with GISN. It is conceivable in this context that the moral-political benefit (namely legitimacy) of the network would be fully restored in the eyes of low-income countries, as they would be empowered to compete and cooperate on a more equitable footing.

Similarly, expanding the GAP would benefit those countries that were largely content with the former system as well. Given that further expansion of the GAP would likely result in increased technical capacity for disease surveillance and outbreak response amongst low-income countries, it is plausible that some countries that had not previously been able to contribute data and virus samples to the WHO's GISN would be enabled to do so. Expanded surveillance coverage and improved outbreak response capacity would, in turn, increase overall pandemic preparedness and global health security, and increase the likelihood that disease

outbreaks could be better controlled at source. Moreover, the inclusion of even more countries would enhance the legitimacy of GISN by strengthening its global reach and coverage, thereby reflecting positively on the network's legitimacy.

Of course, it has to be acknowledged the contemporary economic climate is not particularly conducive to securing additional funds for extending the GAP. The 2008 global financial crisis has, for instance, placed considerable pressure on governments around the world to reduce public spending and find efficiency savings wherever possible. Added to this, pandemic fatigue has firmly set in amongst donors and the wider public health community which have been in a state of heightened alert and risk aversion/crisis management since 2005. While the 2009 H1N1 pandemic proved to be less severe than initially feared in terms of human lives lost, the event has altered the overall perception of risk relating to such events. Rather than serving to reinforce that the threat from pandemic influenza is both genuine and ongoing, the 2009 H1N1 pandemic has had the converse effect, dispelling both the sense of immanency and severity of the threat. In this post-H1N1 environment, calls for further investment in pandemic preparedness are unlikely to be met with much enthusiasm, particularly in the wake of a new international agreement that ostensibly is meant to address concerns around equitable access to vaccines.

Equally, however, it is fair to say that the risk of another influenza pandemic has not dissipated. New cases of human H5N1 infections continue to be reported at the time of writing (WHO 2011c). Add to this that the source of new H5N1 infections – namely domestic and wild birds – remains uncontrolled, the prevalence of the virus throughout Asia where humans often live in close proximity to pig and bird livestock that serve as “melting pots” for the virus, and the instability of influenza viruses' genetic composition that allows it to easily mutate, it is easy to appreciate that a H5N1-inspired pandemic remains conceivable. Even though if the H5N1 does not achieve effective human-to-human transmission, the reality is that global pressures such as population growth and movement, urbanization, changes in food production, agriculture and land use, water and sanitation, and increasing levels of drug resistance, will continue to contribute to the emergence of new infectious diseases as well as facilitate the spread of existing diseases such as pandemic influenza (Coker, Hunter, Rudge, Liverani and

Hanvoravongchai 2011). In such an environment, it would be unfortunate for the international community to fall into complacency, and further work remains to ensure equitable access to such essential medicines as influenza vaccines.

Conclusion

The above case study into 2011 Pandemic Influenza Preparedness Framework highlights several of the inherent tensions and risks associated within multilateralism and the emergent nature of global health governance at the beginning of the twenty-first century. While the determinants of health and their outcomes are increasingly transborder, posing new risks to human populations, the world lacks the appropriate institutional structures, mechanisms, and forms of governance to deal effectively with them. Unfortunately, by failing to satisfactorily address either set of the negotiating parties' expectations relating to the functional and moral-political benefits, and by failing to engage with the various market-based structural inequalities that currently inhibit equitable access to influenza vaccines, the PIPF agreement has also regrettably failed this test.

Indeed, for those countries that supported Indonesia's actions the intended functional benefit of entering the negotiations was to reform the GISN's processes and systems to facilitate equitable access to influenza vaccines and other benefits. Through the need for compromise though, in part due to fundamental disagreements over the role and authority of categories of actors within GHG, only minimal changes have been achieved with the corresponding outcome that the legitimacy of the GISN has also failed to be fully restored. Likewise, for those countries that were largely supportive of the former system, due to the time taken, the fact that the negotiations failed to result in the swift resumption of virus sharing, and that the negotiations prompted countries to argue for more stringent regulations under an alternative framework – the CBD's Nagoya Protocol – the process also failed to meet the functional and moral-political expectations of these actors.

The paper has also argued that the resultant PIPF agreement has failed to sufficiently engage with, and find appropriate solutions to, the current market-based structural hurdles that prevent equitable access to vaccines, namely limited overall global production capacity, the

prevalence of APAs, and the need for more private sector investment. In this way, it could be argued that global health security has been inadvertently hampered by what could be termed a diplomatic success. As any student of international relations can attest, history is replete with many such examples. Equally though, it is important to remember that diplomacy can, and does, take many forms; and even after the ink has dried on international agreements, some form of action is usually required to give effect to a new treaty. Seen in this light, the quality of the document that emerged from the virus sharing negotiations is perhaps not as important as if the talks eventually achieve the objective they set out to accomplish. With this in mind we have sought to make the case for further expansion of the WHO's *Global Pandemic Influenza Action Plan to increase Vaccine Supply* which, we maintain, offers the international community's best chance in tackling the various challenges associated with achieving more equitable access to vaccines. The reforms that would accompany an expansion of this program would also arguably address the majority of concerns held by the former negotiating parties of the virus sharing talks, meeting the original functional and moral-political objectives.

Multilateral processes are fraught endeavours at the best of times, prone to failure, and almost always resulting in an outcome that is less than ideal. Such is the nature of multilateralism. To some extent, whether such multilateral processes are successful depends upon the eye of the beholder. If one holds that such methods are useful only if they achieve tangible results that culminate in positive change, one is likely to be regularly disappointed. If, however, one also sees benefit in the process and practice of assembling potentially diametrically opposed actors to talk through common challenges and gain an appreciation of each other's viewpoint, even though change may only be incremental, then such processes can still be viewed as profitable. Viewed in this light, it could be argued the virus sharing negotiations were a success. Either way, even taking this into account does not invalidate the critical importance of, and need for, collectively-agreed solutions to collective action problems. The international community currently confronts a raft of such problems, ranging from global financial crises, to pandemics, to conflicts, wars, and natural disasters. If left to confront these challenges individually, any government's capacity and resources to respond can be easily overwhelmed. Only together through cooperation and an agreed sense of purpose can

countries hope to meet these challenges and overcome them. Multilateralism, for all its faults, is and remains our best hope in achieving this.

References

- Anjani, K. 2009. 'Indonesia says no policy change on bird flu samples'. Reuters AlertNet, 24 October 2009. Accessible: <http://www.alertnet.org/thenews/newsdesk/JAK449808.htm> (accessed 30 October 2009).
- Anonymous. 2008a. 'Indonesia agrees to hand bird flu information to new online database'. *The Star*, 15 May 2008. Accessible: <http://thestar.com.my/news/story.asp?file=/2008/5/15/apworld/20080515133940&sec=apworld> (accessed 23 July 2010).
- Anonymous. 2008b. 'Universal Influenza Vaccines Tested Successfully in Humans'. Science Daily, 25 January 2008. Accessible: <http://www.sciencedaily.com/releases/2008/01/080124185522.htm> (accessed 28 July 2010).
- Anonymous. 2010. 'France begins H1N1 vaccine sell-off'. Al-Jazeera.Net. 4 January 2010. Accessible: <http://english.aljazeera.net/news/europe/2010/01/201014935778838.html> (accessed 26 July 2010).
- Belford, A. 2008. 'Indonesia's bird flu warrior takes on the world'. *Macau Daily Times*, 8 December 2008. Accessible: http://www.macaudailytimesnews.com/index.php?option=com_content&task=view&id=20100&Itemid=32 (accessed 23 July 2010).
- Burci, G. L. and Vignes, C. 2004. *World Health Organization*. The Hague: Kluwer Law International.
- Cohen, J. 2010. 'Laurie Garrett Interview: U.S. Global Health Leader MIA on Swine Flu'. *ScienceInsider*, 28 July 2009. Accessible: <http://news.sciencemag.org/scienceinsider/2009/07/laurie-garrett.html> (accessed 28 July 2010).
- Coker, R., Hunter, B., Rudge, J., Liverani, M. and Hanvoravongchai, P. 2011. 'Emerging infectious diseases in southeast Asia: regional challenges to control'. *Lancet*. 377(9765): 599-609.
- Davies, Sara. (2008): "Securitizing infectious disease" *International Affairs*. 84(2): 295-313.
- Earth Negotiations Bulletin. 2010. 'Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010'. *Earth Negotiations Bulletin*. 9(527):1-16. Accessible: <http://www.iisd.ca/biodiv/rabs9/> (accessed 26 July 2010).
- Fedson, D.S. and Dunnill, P. 2007. 'From Scarcity to Abundance: Pandemic Vaccines and Other Agents for "Have Not" Countries', *Journal of Public Health Policy*. 28(3): 322-340.

Fidler, D.P. 2008. 'Influenza Virus Samples, International Law, and Global Health Diplomacy'. *Emerging Infectious Diseases*. 14(1): 88-94.

Garrett, L. and Fidler, D.P. 2007. 'Sharing H5N1 Viruses to Stop a Global Influenza Pandemic'. *PLoS Medicine*. 4(11): 1712-1714.

Holbrooke, R. and Garrett, L. 2008. 'Sovereignty' That Risks Global Health'. *The Washington Post*, 10 August 2008. B07. Accessible: <http://www.washingtonpost.com/wp-dyn/content/article/2008/08/08/AR2008080802919.html> (accessed 28 July 2010).

[author, 2010.]

Kilbourne, E.D. 2006. 'Influenza Pandemics of the 20th Century'. *Emerging Infectious Diseases*. 12(1): 9-14.

Khoo, C.C. 2010. 'Equitable Access to Pandemic Flu Vaccines'. Third World Network, 31 March 2010. Accessible: <http://www.twinside.org.sg/title2/health.info/2010/health20100303.htm> (accessed 26 July 2010).

Lee, K. 2003. *Globalisation and Health: An Introduction*. London: Palgrave Macmillan.

Lee, K. and Fidler, D.P. 2007. 'Avian and pandemic influenza: Progress and problems with global health governance', *Global Public Health*. 2(3): 215-234.

Louie, J.K., Acosta, M., Winter, K., Jean, C., Gavali, S., Schechter, R., Vugia, D., Harriman, K., Matyas, B., Glaser, C.A., Samuel, M.C., Rosenberg, J., Talarico, J. and Hatch, D. 2009. 'Factors Associated With Death or Hospitalization Due to Pandemic 2009 Influenza A(H1N1) Infection in California'. *JAMA*. 302(17): 1896-1902.

Mara, K. 2009. 'Disagreements Remain In WHO Talks On Virus-Sharing After Chan Proposal'. *Intellectual Property Watch*. 22 October 2009. Accessible: <http://www.ip-watch.org/weblog/2009/10/22/disagreements-remain-in-who-talks-on-virus-sharing-after-chan-proposal/> (accessed: 12 August 2010).

Narlikar, A. 2010. Introduction. In *Deadlocks in Multilateral Negotiations: Causes and solutions* edited by Amrita Narlikar. Cambridge: Cambridge University Press.

Sedyaningsih, E.R., Isfandari, S., Soendoro, T. and Supari, S.F. (2008) 'Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia', *Annals Academy of Medicine*. 37(6): 482-488.

Sheridan, C. 2005. 'The business of making vaccines'. *Nature Biotechnology*. 23(11): 1359-1366.

Sturcke, J. and Bowcott, O. 2010. 'Drug companies face European inquiry over swine flu vaccine stockpiles'. *The Guardian.co.uk*, 11 January 2010. Accessible: <http://www.guardian.co.uk/world/2010/jan/11/swine-flu-h1n1-vaccine-europe> (accessed 26 July 2010).

Supari, S.F. 2008. *It's Time for the World to Change: in the spirit of dignity, equity, and transparency. Divine Hand Behind Avian Influenza*. Jakarta: P.T. Sulaksana Watinsa Indonesia.

Touval, S. 2010. 'Negotiated cooperation and its alternatives'. In *International Cooperation: The Extents and Limits of Multilateralism* edited by I. William Zartman and Saadia Touval. Cambridge: Cambridge University Press, 78-91.

United Nations Environmental Programme. 2011. *Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity*. Canada: Secretariat on the Convention on Biological Diversity. Accessible: <http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf> (accessed 3 June 2011).

Walsh, F. 2010. 'Millions of doses of swine flu vaccine to be off-loaded'. BBC News, 8 January 2010. Accessible: http://www.bbc.co.uk/blogs/thereporters/ferguswalsh/2010/01/tens_of_millions_of_doses_of_swine_flu_vaccine_to.html (accessed 26 July 2010).

WHO. 2005. *Basic Documents, Forty-fifth Edition*. Geneva: World Health Organization.

WHO. 2006. *Global pandemic action plan to increase vaccine supply*. Document WHO/CDS/EPR/GIP/2006.1, Geneva: World Health Organization.

WHO. 2007a. *The world health report 2007: a safer future: global public health security in the 21st century*. Geneva: World Health Organization.

WHO. 2007b. *WHO Interim Protocol: Rapid operations to contain the initial emergence of pandemic influenza*. Geneva: World Health Organization. Accessible: http://www.who.int/csr/disease/avian_influenza/guidelines/draftprotocol/en/index.html (accessed 10 December 2010).

WHO. 2007c. 'Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses. List of Participants'. Document A/PIP/IGM/DIV/2_Rev.1. Accessible: http://apps.who.int/gb/pip/pdf_files/PIP_%20IGM_DIV2Rev1.pdf (accessed 28 July 2010).

WHO. 2008a. 'Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits. Intergovernmental Meeting: report of progress to date'. Document EB122/5, 17 January 2008. Accessible: http://apps.who.int/gb/ebwha/pdf_files/EB122/B122_5-en.pdf (accessed 31 May 2011).

WHO. 2008b. 'Draft Chair's text – Pandemic influenza preparedness: multilateral framework for the sharing of influenza viruses and access to vaccines and other benefits'. Document A/PIP/IGM/WG/6 (Draft), 29 June 2008. Accessible:

http://www.sovereigndeed.com/PDF/pubs_avian-flu-chair-text-2008.pdf (accessed 31 May 2011).

WHO. 2009a. 'Progress in pandemic influenza vaccine preparedness'. *WHO Press Release*, 24 February 2009. Accessible:

http://www.who.int/immunization/newsroom/medianote_progress_Pandemic_influenza_feb09/en/ (accessed 28 July 2010).

WHO. 2009b. *The Global Action Plan to increase supply of pandemic influenza vaccines: Report of the second meeting of the Advisory Group, Pune, Maharashtra, India*. Document WHO/IVB/09.07. Accessible: http://whqlibdoc.who.int/hq/2009/WHO_IVB_09.07_eng.pdf (accessed 28 July 2010).

WHO. 2009c. 'Influenza vaccine manufacturers, 13 May 2009'. Accessible:

http://www.who.int/csr/disease/influenza/Influenza_vaccine_manufacturers2009_05.pdf (accessed: 12 August 2010).

WHO. 2010a. Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO. 19 November 2010. Accessible:

http://www.who.int/csr/disease/avian_influenza/country/cases_table_2010_11_19/en/index.html (accessed 2 December 2010).

WHO. 2010b. Avian Influenza ("bird flu") Factsheet. Accessible:

http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html (accessed 2 December 2010).

WHO. 2010c. Pandemic (H1N1) 2009 – update 83. Accessible:

http://www.who.int/csr/disease/swineflu/laboratory15_01_2010/en/index.html (accessed 2 December 2010).

WHO. 2010d. 'Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: Outcome of the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: of influenza viruses and access to vaccines and other benefits: Report by the Director-General'. Document A63/48. Accessible:

http://apps.who.int/gb/e/e_wha63.html (accessed 26 July 2010).

WHO. 2010e. 'Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: Outcome of the process to finalize remaining elements under the pandemic influenza preparedness framework for the sharing of influenza viruses and access to

vaccines and other benefits: Report by the Secretariat'. Document A63/4. Accessible: http://apps.who.int/gb/e/e_wha63.html (accessed 26 July 2010).

WHO. 2010f. 'Public health, innovation and intellectual property: global strategy and plan of action. Report by the Secretariat'. Document A63/6. Accessible: http://apps.who.int/gb/e/e_wha63.html (accessed 26 July 2010).

WHO. 2011a. 'Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits'. Accessible: http://www.who.int/csr/disease/influenza/pip_framework_16_april_2011.pdf (accessed 30 May 2011).

WHO. 2011b. 'Technical studies under resolution WHA63.1. Final document'. Accessible: http://www.who.int/csr/disease/influenza/technical_studies_under_resolution_wha63_1_en.pdf (accessed 30 May 2011).

WHO. 2011c. 'Avian influenza – situation in Indonesia - update 4'. Accessible: http://www.who.int/csr/don/2011_05_13/en/index.html (accessed 31 May 2011).

Table 1: Policy considerations for LMICs on accessing influenza vaccines

	SEASONAL INFLUENZA	PANDEMIC INFLUENZA
LIKELY MORBIDITY	LOW TO MEDIUM	HIGH
LIKELY MORTALITY	LOW	LOW TO HIGH
PROBABILITY OF OCCURRENCE WITHIN FIVE YEARS	HIGH	LOW
COST	HIGH	HIGH
AVAILABILITY IN LMICs	LOW	LOW