From SARS to avian influenza: the role of WHO in global governance of pandemic risks.

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Congrès de l'AFSP, Strasbourg, 31 août – 2 septembre 2011

Summary

As globalization continues to blur borders and increase interdependence, risk transcends national borders, causing major challenges in risk governance. This is particularly well illustrated in the health sector. Epidemics and pandemics know no borders and are often characterized by a high level of uncertainty regarding the causality of risk and its potential social and economic consequences. How these risks are addressed at the international level and what is the role of international organizations in facing them lie at the heart of this paper. The analysis of the Severe Acute Respiratory Syndrome (SARS), and avian influenza (H5N1) cases shows the emergence of global risk governance processes and the key role that multilateral institutions, in particular the World Health Organization (WHO), play within them.

1. Introduction

As globalization continues to blur borders and increase interdependence, risk transcends national borders, causing major challenges in risk governance. While risk interdependence and the increased complexity of the international environment require the formulation of global responses to global risks, risk governance processes to cope with them are emerging (Organization for Economic Cooperation and Development (OECD) 2003); (Renn, Walker et al. 2008). The effects of globalization render the question of risk governance and the role of international organizations in this emerging process particularly relevant. This is particularly well illustrated in the health sector. Epidemics and pandemics know no borders and are often characterized by a high level of uncertainty regarding the causality of risk and its potential social and economic consequences.

In this paper, we seek to show how the World Health Organization (WHO) has positioned itself as a leading organization in the governance of pandemic risks and to shed light on the essential

organizational features of these emerging global risk governance processes. In particular, we will explain how WHO gained the capacity and legitimacy for action in pandemic management and how it conducted a science based risk assessment that set the bases for the formation of the international responses to the Severe Acute Respiratory Syndrome (SARS) and avian influenza H5N1.

This paper is based on the results of two empirically-based case studies that were completed between 2005 and 2009: the SARS crisis that took place from February 26th 2003 to July 5, 2003; and the H5N1 avian influenza from February 2003 to December 2008. Our study was based on the qualitative analysis of documents - with a focus on official documents of organizations - and interviews. For each case study, we conducted a total of about 5-10 semi-directed interviews of WHO's personnel and other actors in the field of global risk governance. Secondary sources such as news, articles, studies and books also were consulted in order to add another perspective to the analysis. To a lesser extent, complementary sources such as information gathered during conferences and communications with certain experts were included as well.

1.1 Global risk governance challenges

Recent risk literature converges on one aspect: risk assessment and risk management pose major challenges in all fields of our interconnected societies. Roles and responsibilities of the actors as well as structures and processes to assess risk and design responses are often not clearly defined. Which bodies should be ultimately in charge of the risk governance process and handle the consequences of the risk is not always clearly established.

Firstly, risks have become more uncertain, complex and global, while risk governance processes to cope with them are emerging. While governance has become a very popular topic over the past twenty years and implies that at all levels, governance outputs are based on the interplay between governments, industries, and academia, as well as civil society (Renn 2008, 8-9), risk governance, and in particular global risk governance, remains a discipline in its infancy. Risk governance has emerged as a concept over the past ten years and is meant to include more than risk analysis practices that have traditionally encompassed with various degrees of separation risk assessment, risk management and risk communication. Risk governance includes consideration of the legal, institutional, social, and economic contexts in which a risk is evaluated, and involvement of the actors and stakeholders who represent them (Renn 2008, 8-9), and can be applied at all levels. This concept is intimately linked to the complexity of modern risks, the role of science and experts, and the importance of trust and stakeholder participation (Van Asselt and Renn 2011). In its report "Emerging systemic risks in the 21st Century: An Agenda for Action" (Organization for Economic Cooperation and Development (OECD) 2003) proposed recommendations to improve the governance

of “systemic risks”, and argued for a coherent and common risk approach. In parallel, the development by a non-profit organization based in Geneva, the International Risk Governance Council (IRGC), of a risk governance framework that may be applied by various stakeholders, also represents an attempt to provide a response to these challenges (Renn 2008). However, these writings focus on potential improvements to current models of risk governance, or propose the implementation of a new model to better integrate the context and actors’ concerns and perceptions, but do not emphasize the respective roles of the actors within emerging global risk governance processes and how they could be organized at the global level.

Besides, risk analysis models that have been developed and applied over the past thirty years have become insufficient to address these risks. The special issue of the Journal of Risk Research of April 2011 dedicated to risk management underlines the current difficulties to assess uncertainties, establish adequate risk steering mechanisms and processes and form balanced responses in regard to scientific knowledge about the risk, its origins and consequences, the logic of precaution and the costs of action. Risk governance processes suffer from a lack of adequate risk frameworks, a shortage of risk harmonization procedures and an interdisciplinary deficit approach to risk. This is partly due to the fact that risk governance relies on risk analysis frameworks that were developed in corporate or institutional contexts, and were often context specific (actuarial risk framework, science-based risk analysis framework, economic or business risk management frameworks). It is the case of the “Red book” risk analysis framework that was developed in the United States in 1983 and updated in 2009 (National Research Council (U. S.) 2009) and that has progressively been recognized as an international standard. This framework is used by governments, international organizations, and other entities worldwide and is composed of three interrelated components with various degrees of separation: risk assessment (science based evaluation of risk), risk management (development and evaluation of regulatory options and/or decisions), and risk communication (both internal and external). However, risk approaches remain often based on past experience, which is not sufficient to address risks that depart from past data, such as new infectious diseases or large scale disasters (Organization for Economic Cooperation and Development (OECD) 2003). The identification, capture and analysis of the contributing factors to the emergence of such risks also represent an additional difficulty for practitioners (International Risk Governance Council 2010, 5). The possibilities of estimating risks (risk assessment) and to reduce or control them through policy measures (risk management) are under pressure (Van Asselt and van Bree 2011, 401) due to the increased level of uncertainty prevailing in the emergence of a new disease, the development of a new technology and large scale disasters of various natures. This is particularly well illustrated in the assessment of pandemic risks under WHO. This paper is essentially about global risk governance in health and aims

at contributing to the emerging literature in this field. In particular, it may increase understanding of the risk-analysis practices carried out within WHO and its role within the emerging processes of global risk governance.

1.2 International organizations and global risk governance

Over the past fifteen years, international organizations have been increasingly involved in assessing and managing risks. They have been shaping guidelines and policies aimed at containing or reducing risk and have also contributed to the development of international regulatory approaches for example in the food safety sector (World Health Organization and Food and Agriculture Organization of the United Nations 2006).

In addition, international organizations have developed capacities in terms of international leverage, access to information, human and financial resources, and infrastructures, in addition to networks of experts to address international issues. They have gained in independence from their constitutive body, the states, and have emerged as actors who have the capacity to initiate, inform and drive globally relevant projects. They are able to influence states with expectations about rules and correct behavior (Keohane and Martin 1995). They are also embedded in larger, intertwined networks with other institutions and partners in the public and private sector, as well as in the civil society, which brings to these institutions a greater variety and representation of ideas and means of actions.

Finally, they have built expertise networks that are sources of information exchange and advice across fields of activities and countries. For example, the WHO is an international organization, a regime with the International Health Regulations (IHR), and a network at the same time. This network encompasses WHO headquarters, regional and country offices of the organization, scientific experts, partnerships with the private sector, and cooperation undertaken with other international organizations and non-governmental organizations. Driving global governance processes is within their capabilities and scope of action, as demonstrated by the leading role that WHO played in tobacco control. WHO was able to mobilize a broad range of stakeholders, including representatives of states, scientific experts, international institutions, and members of the civil society, in order to federate their views and coordinate the process that led to the adoption of the Framework Convention on Tobacco Control (FCTC) in 2003 (Lee 2003). While international organizations have positioned themselves as important players in global risk governance processes (Brender 2010) responding to the growing needs for more international consultation and cooperation in dealing with emerging global risks, studies have mainly addressed more participative forms of risk governance at national levels (Callon, Lascoumes et al. 2001) and international levels (Renn 2008) or focused on the role of actors from the civil society both at national and international levels.

The emergence of SARS in 2003, a previously unknown disease that was killing people and for which no cure existed, offers an interesting example of how WHO's methods of addressing risk contributed to a successful containment of the disease in less than four months, limiting the number of human cases to 8'000 in 29 countries with 800 deaths. According to some authors, the perception of risk of a SARS pandemic resulted in a disproportionate economic impact (Smith 2006). Nevertheless, the necessity of contending with SARS was considered an historic moment in the governance of risks of global infectious disease (Fidler 2004). The effort represented the first successful management of an emerging infectious disease in globalized societies and economies of the 21st century.

The resurgence of the virus A (H5N1) in 2003 in Hong Kong during the SARS outbreak and the subsequent outbreaks in Asia in 2004 have made this virus a strong candidate for a human influenza pandemic. Therefore, explaining how H5N1 avian influenza has been addressed at the international level is important. While the total number of human cases at the end of 2008 was limited to 393 cases in 15 countries, out of which 248 deaths occurred (World Health Organization - Epidemic and Pandemic Alert and Response 2009), the case fatality ratio is high at approximately 63%. A human influenza pandemic originating from a virus against which populations are not immune could have a significant worldwide impact in terms of human lives lost and burdens on public health systems, as well as causing social disruptions and economic costs. In other words, this virus A (H5N1), infecting domestic animals such as poultry, ducks, and even pigs, is susceptible to evolving into a highly pathogenic human form that could easily contaminate humans and efficiently transmit among them. The Spanish Influenza of 1918-1919 that generated over 40 million deaths worldwide,(Taubenberger 2003) as compared to the estimated 20 million deaths due to World War I, is often cited as the most striking example of a virulent influenza pandemic

2. Governance of SARS and Avian influenza H5N1 pandemic risks

2.1. Context

The SARS outbreak and avian influenza H5N1 occurred in an international context of growing concern about infectious diseases as a resurgent public health issue. Several infectious disease outbreaks, such as cholera in South America in 1991, pneumonic plague in India in 1994, and Ebola hemorrhagic fever in Africa in 1995, had demonstrated the need for stronger international cooperation in forming and implementing responses and in sharing the latest accurate information during the course of the outbreak in a timely way (MacLean 2005). In 1996, WHO began setting up a new emerging infectious disease program to better detect and respond to such outbreaks (World Health Organization 2006). This initiative resulted in the establishment in 1999 of the Global Public Health Intelligence Network

(GPHIN)(Public Health Agency of Canada 2004), which scanned news feeds in English and French to detect outbreaks; and in the launch in 2000 of the Global Outbreak Alert and Response Network (GOARN), bringing together some 120 partners to provide experts for field missions (World Health Organization - Epidemic and Pandemic Alert and Response 2009).

Since the resurgence of the virus A (H5N1), WHO engaged in pandemic preparedness activities, cooperating with leaders of other organizations and member states. These activities were not only declared useful in preparation for the next pandemic, be it of an avian influenza H5N1 source or of another origin, as well as for new infectious disease, but also as preparation for a microbiological attack. In an international post-September 11th and post-SARS context, this combination of arguments enhanced active international cooperation as well as national initiatives. In fact, the resurgence of certain infectious diseases and the apparition of new diseases, such as SARS, have made countries' leaders aware of the consequences that these diseases may generate in terms of human lives and burden on public health, as well as causing social disruptions and economic costs. For example, the G8 leaders reaffirmed their support of the WHO-administered Global Outbreak Alert and Response Network (GOARN), to the FAO and the OIE as well as the UN System Influenza Coordination Office (UNSIC) and international financial institutions in addressing the global threat of avian influenza (Official website of the G8 summit 2006 in Saint-Petersburg 2006). Therefore, significant involvement is expected from international organizations, such as WHO or OIE, to coordinate actions and carry out protection measures.

2.2. WHO's legitimacy for action

The SARS case raises an important issue. In 2003, the International Health Regulations (IHR) of 1969 (revised 1981), which were the only legally binding international instrument for managing infectious diseases with the potential to spread internationally, did not apply to SARS. In fact, these rules prescribed the implementation of mostly sea and air transportation measures to prevent the international spread of only three communicable diseases: cholera, plague, and yellow fever. International organizations historically have derived their right to rule from international agreements such as the IHR. States delegate certain competences to the organization to issue rules and ensure their compliance by the parties to these regulations. This rule-based legitimacy is important, as it defines the frame within which the institution can act, but the perception of other actors that the institution has the right to rule and a certain degree of compliance to its recommendations matters as well (Keohane and Buchanan 2006).

WHO's legitimacy could not have been derived from IHR 1969, which did not apply to SARS. Its putative legitimacy was instead derived from generally accepted practice as set forth in provisions of

the IHR revision project 2002. The revision of the International Health Regulations had already been launched, and if WHO's actions were inspired by the 2002 project, these measures had not been approved by member states prior to their application. Thus, IHR, the legally binding instrument, did not support and justify WHO's actions during the crisis, actions that complied mostly with a non-legally binding draft of rules. Member states generally accepted and applied WHO's recommendations, and its actions were for the most part validated by the eventual adoption of applicable resolutions by the World Health Assembly in May 2003. Although some states were either reluctant to cooperate (e.g., China) or criticized travel restrictions (e.g., Canada, China, and Taiwan), the authority of WHO to act as global coordinator with the power to issue recommendations to be enforced by states in order to control spread of the disease was not fundamentally questioned. States could have opposed WHO by refusing to cooperate and report cases, by trying to form coalitions to block the resolutions that was proposed at the World Health Assembly, or by launching a media campaign denying the legitimacy of the organization to act. From a state perspective, implementation of new practices preceded the formal approval of the rules and the documentation of risk assessment plans and mechanisms, resulting in an action-based legitimacy rather than a rule-based legitimacy.

This action-based rather than rule-based legitimacy was for the most part validated by the World Health Assembly resolutions of May 2003. The World Health Assembly Resolution on SARS and the IHR resolution, which were approved by member states, converted WHO's practices in SARS risk assessment and case management into formal rules. For example, the SARS resolution urged state members to apply WHO-recommended guidelines on surveillance, case definitions, case management, and international travel; to report cases promptly and transparently and provide other requested information to WHO; to enhance and strengthen cooperation with WHO; to request WHO support and assistance for the control measures; and to exchange information within the networks. The IHR resolution also authorized WHO to employ unofficial sources as a starting point in its outbreak verification process. A posteriori, member states approved WHO's actions and confirmed an action-based legitimacy gained through its management of the SARS outbreak.

On the one hand, WHO's actions during the SARS crisis went beyond the IHR revision project; on the other hand, the practice developed during the SARS outbreak anticipated rules that would be included in the revised IHR as finally approved in 2005. For instance, the scope of diseases would be extended to include public health emergencies of international concern (PHEIC). But authority to respond to emergencies of international relevance that could lead to the issuance of WHO recommendations under International Health Regulations Revision Project of 2002 (and that were

applied in the SARS outbreak) was amended in the final version of the revised IHR 2005 to require consultation with state parties (World Health Organization 2002) before the issuance of WHO's communications. This consultation was perceived as one way to better preserve the sovereignty of states in the process, although it does not preclude WHO to issue recommendations without the state's consent.

The IHR 1969 did not apply to H5N1 avian influenza for the same reasons as it did not apply to SARS. The resolution on the revision of IHR (World Health Assembly 2003), adopted by the World Health Assembly in May 2003, provided a legal basis for WHO action but did not cover the whole range of activities as prescribed in the revised IHR project in 2002. While states' officials are urged to establish focal points and ensure collaboration with agencies involved in animal care, they do not have the obligation to notify WHO of the avian influenza disease. Under this resolution, WHO can use non-official sources of information reporting outbreaks, issue alerts in the case of a serious threat after having informed the government(s) officials concerned, collaborate with national authorities in assessing the severity of the threat and adequacy of control measures, and conduct on-the-spot studies to ensure that appropriate control measures are being employed. This resolution provided a limited formal legal basis for action until April 2006 when the World Health Assembly adopted a resolution(World Health Assembly 2006) on the early and voluntary application of the IHR (2005) to strengthen pandemic preparedness and response, in particular in surveillance, reporting, information-sharing, and setting up a National IHR Focal Point. The revised IHR were adopted in May 2005 (IHR 2005) to come into force on June 15, 2007. Early adoption was applied by states willing to do so, and on June 15, 2007, the IHR 2005 came into force and provided the formal legal basis for WHO actions.

In practice, the provisions included in the draft of the revised IHR that was submitted to the WHO Executive Board in January 2004 were applied in regard to the outbreak of avian influenza. Although the final version of IHR included some changes in scope and procedure, such as the joint use of a list of diseases and the concept of an event that can consist of a PHEIC, the provisions remained essentially similar. While the revised IHR 2005 did not contain the possibility of on-the-spot studies, as mentioned in the resolution on IHR, authors of the IHR 2005 linked the notification with the possibility of seeking assistance from WHO as an incentive for states to report an outbreak. The Annex II in its generic form, pertaining to a concept and not a list of diseases, was available to state officials for assessment and notification. In fact, in the case of the avian influenza, national authorities of affected areas spontaneously reported the outbreaks and the number of cases to WHO that initiated the verification and assessment process in return. The importance of timely and

transparent reporting might have been influenced by the SARS experience. For Vietnam, it was also a way to seek assistance and have investigations on site about the transmission on the disease in 2004.

WHO's legitimate basis for action in the case of Avian influenza is both action-based and rule based. Until the early adoption of the IHR in May 2006 or the entry into force on June 15, 2007, the formal legal basis for action remained the IHR 1969, and the resolution on IHR of May 2003 that was limited in its scope. During that period, the provisions of the draft of the revised IHR were used as the basis for action and were generally accepted by states.

2.3. Science-based risk assessment under WHO: framework, expertise and process

In its World Health Report 2002 "Reducing Risks, Promoting Healthy Life," the organization defines risk "a probability of an adverse outcome, or a factor that raises this probability," and provides a framework for risk assessment consisting of "a systematic approach to estimating the burden of disease and injury due to different risks."(World Health Organization 2002, 8). This risk assessment framework is based on the "Red Book" Framework and seeks to guide countries and the organization itself to assess risk in order to take effective countermeasures and improve health.

2.3.1. Framework

WHO's risk assessment framework consists of four major steps (World Health Organization 2002, 10). The first step is hazard identification (i.e., virus X causes disease Y). Second is an exposure assessment to estimate the extent to which a given population is exposed to the hazard. Third is a dose-response (or cause-effect) assessment that relates the probability of a health effect to the degree of exposure. Fourth is a risk characterization that consists of calculating the estimated health risk, such as the number of people predicted to experience a particular disease for a particular population. This step also includes the estimation and the communication of uncertainties. A combination of this risk assessment framework with the "Guiding Principles for International Outbreak Alert and Response"(World Health Organization - Epidemic and Pandemic Alert and Response) and the notification and risk assessment instrument (that will be integrated as Annex 2 of the revised IHR) was applied in both the SARS and avian influenza H5N1 cases. These procedures were integrated into the revised IHR 2005 and formalized in the WHO Event Management for International Public Health Security and focus on surveillance, detection, verification, and risk assessment of the event to determine whether it does indeed represent an international public health risk. The notification instrument about events that may cause public health emergencies of international concern that was later included in the revised IHR as Annex 2 was available as draft for

use for both the SARS and avian influenza cases. How the disease is spreading internationally; whether it is a known or an unknown disease; its incidence, morbidity, and mortality; the vulnerability assessment of populations, infrastructures and health care capacities—all of these factors inform initial decisions about how to handle the event. Since WHO considers risk assessment to be an iterative process, the method suggests continuous investigations to increase the level of information, which is of particular importance when new diseases emerge such as SARS. At the time of the SARS outbreak, there was no risk assessment method specific to the disease, the nature of which was then almost completely unknown. In 2004, WHO would publish a SARS-specific method of risk assessment to be used as a protocol in case SARS should resurge.

Both SARS and H5N1 Avian influenza met the four criteria to be considered as a public health emergency of international concern: seriousness of the disease in terms of public health impact (high mortality); unexpectedness (unusual character of the disease that could result in a pandemic); international spread (regional and intercontinental spread); and risk of international travel and trade restrictions (travel precautions recommended in the case of SARS and possible impact on poultry trade in the case of avian influenza H5N1). If two of these criteria are met, state parties shall notify WHO under Article 6 of the IHR. The determination of a Public Health Emergency of International Concern (PHEIC) represents a key element of the risk assessment, as it is the triggering event for WHO to activate its network and organize an international response. In its first public statement of January 13, 2004, WHO already had expressed its concern about the regional outbreak in poultry in Asia, the human cases detected in Vietnam, and the instability of the virus that could change into a form transmissible to humans and for which humans would not have immunity (World Health Organization - Epidemic and Pandemic Alert and Response 2004). The resolution of the World Health Assembly of 2006 clearly referred to the concept of PHEIC to follow up on human cases of avian influenza (World Health Assembly 2006). Based on a proposal made by Thailand to the Executive Board of WHO in May 2005, a resolution regarding the early application of selected IHR 2005 provisions on a voluntary basis was adopted during the World Health Assembly of 2006, which reinforced the application of this risk assessment procedure and the use of this notification instrument (World Health Assembly 2006).

The Influenza Pandemic Plan 1999 also provided some guidance for WHO's actions. Since SARS was at first mistakenly associated with A(H5N1) influenza and only later confirmed to be a new disease, initial response included activating the influenza surveillance network. Although it may not have been directly applied once influenza was finally ruled out, the methodology of the influenza pandemic plan influenced WHO staff working on the SARS outbreak, for these personnel had also

been involved in the influenza program. The 1999 influenza preparedness plan included guidelines for tracking the risk and its possible sources, as well as for determining the causal chain of a pandemic risk; these guidelines were also followed in the SARS case. As prescribed by the influenza plan, WHO coordinated laboratory research to determine the characteristics of the new virus and of SARS disease, enhanced surveillance, and developed a case definition. WHO also provided guidelines to national health authorities regarding the surveillance, risk groups, and case management, including guidance of best available drugs. In addition, WHO set up a SARS task force as prescribed for preparedness level 3 of the influenza plan, which coordinated SARS risk assessment process and response.

The influenza pandemic preparedness plan 1999 (World Health Organization - Department of Communicable Diseases 1999) included a risk assessment of pandemic level. However, the revision process of that plan was started already when the avian influenza H5N1 outbreak occurred and resulted in an acceleration of its revision process and publication of the WHO Global Influenza Preparedness Plan in the fall of 2005. (World Health Organization - Department of Communicable Diseases 2005). The objectives of both plans were two-fold. On the one hand, they provided WHO with a risk assessment method to evaluate an influenza event in terms of potential to result in a pandemic and to decide at which "phase" the world is during each stage of the evolution of knowledge about the disease. On the other hand, these plans were meant to be guidelines for states to prepare their own influenza national preparedness plans. The WHO global influenza preparedness plans provided minimum standards to be achieved by states in order to ensure adequate control and protection measures in the case of a human influenza pandemic.

WHO developed risk assessment methods that could be used jointly to address SARS and avian influenza H5N1 at different levels: at the organizational level in assessing the public health event and leading the scientific assessment of the disease, at country levels in improving national public health policies, and at the disease level in formulating guidelines to be used as standard protocols for known diseases. WHO's risk assessment of SARS was based on consistently combining its overall risk assessment framework, its alert and response method, and elements of the influenza plan. In the case of an outbreak of an infectious disease, the alert and response method, in compliance with the overall risk assessment framework, focuses on assessing the infectious nature of the disease and therefore its potential to spread internationally, taking into account the need to effectively cope with the disease as quickly as possible. WHO mobilized internal and external expertise to complete risk assessment procedures.

2.3.2. Expertise

WHO's organization of expertise was based on the multidisciplinary background of experts, their international track record, and the fact that their work relied on the latest research to be included in the risk assessment. Although there is no consensus on the definition of expertise (and experts), assimilated to scientific expertise in some cases and to privatized expertise (Lascoumes 2005, 25-27) in others, it usually implies the production of specific knowledge for action (Lascoumes 2005, 5). WHO defines an expert as "any person possessing qualifications and/or experience relevant and useful to the activities of the Organization in a field covered by an established expert advisory panel may be considered for appointment as a member of that panel after consultations with the national authorities concerned". The organization also highlights the importance of broadest possible international representation in terms of diversity of knowledge, experience and approaches as a way to better cope and dilute national or sectorial interests.

One new and key feature of the SARS risk assessment was the constitution, the organization, and the role of expertise. For the first time in its history, WHO set up and coordinated virtual networks of virology (11 laboratories in 9 countries), clinical (50 clinicians in 14 countries), and epidemiology experts (32 epidemiologists from 11 institutions in 9 countries) in a continuous real-time cooperative risk assessment. This science-based risk assessment process was meant to be a privileged interface for the exchange of information, research findings, and ideas in order to design and implement the most easily adapted measures. This innovative risk governance mechanism was instrumental in discovering the causal agent, monitoring the clinical course of the disease, and providing epidemiological information to refine the recommended measures. This cooperation was overall a success, which should not minimize the challenge it represented in terms of managing different agendas, priorities, and competition in a race to publish findings.

Another significant aspect of the risk analysis carried out by WHO is the involvement of about 300 experts in the SARS crisis management active in 13 field missions and headquarters activities. Most of the experts came from the field of epidemiology and public health (32%), infection control (15%), and laboratories (6%). The participation of experts in logistics, clinical management, animal health, psychology, administration, and funding remained marginal (less than 1%). Teams were multidisciplinary and combined expertise from different areas, but social sciences remained under-represented or even absent. While economic and funding aspects were taken into account from a macro-perspective, field missions did not systematically address financial considerations nor enlist economists to assess the impact of the disease and countermeasures on local economies. Similarly, no legal experts participated in critical missions to ensure respect for local laws by the field teams as

well as compliance with international regulations in the fields of health and trade. Social dimensions of risk that are essential in assessing risk and designing responses do not seem to have been integrated into the analysis. Finally, although logistical planning was carried out essentially from the WHO Western Pacific Regional Office, logistics specialists were not systematically involved in supporting field missions.

While WHO set up a dedicated task forces to manage SARS and the avian influenza risks, it combined institutional expertise organized through the "traditional" consultation procedure in place at the WHO (member states consultation and international meetings); with a more multi-stakeholder process to assess the influenza pandemic risk and carry out field missions. In the fall of 2005, WHO intensified warning and preparedness activities, with the organization of an international conference in November 2005 jointly organized with FAO and OIE and held in its headquarters in Geneva, gathering professionals from the organization, representatives of member countries, representatives of international organizations and civil society, as well as health experts or consultants to discuss the situation of the avian influenza, to agree upon actions to be taken, and to estimate financial needs to achieve these protection objectives. This conference was followed by the donors' pledging conference in Beijing in January 2006, sponsored by the Chinese government, the European Commission, and the World Bank in order to fund the measures decided. Funds amounting to USD 1.9 billion were pledged during that conference. The participants also took this opportunity to set an agenda for the coming months in terms of the preparation of a protocol for rapid response and containment as well as standard operating procedures in case of the occurrence of an influenza pandemic.

The formation of this protocol followed a completely different process than the influenza preparedness plan. It was prepared and reviewed through technical meetings and focused on technical issues and operations. This protocol was prepared by subject matter experts more than country representatives and was associated with a clinical meeting on how to use drugs and treat human cases. It was also based on a review of the literature that was performed by three specialists, who analyzed the relevancy and soundness as well as reliability of the material to be used in the drafting process. A first draft of the "WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment" was ready on January 27, 2006 (World Health Organization January 27, 2006). This draft was updated to serve as the basis for the work of the Global Technical Meeting on Early Containment Protocol for Pandemic Influenza that was held in Geneva from March 6 to 8, 2006 to discuss influenza pandemic containment strategy.

The purpose of that meeting was to reach a technical consensus on rapid detection, assessment, and response to the signs showing a development of the avian influenza virus towards more transmissibility among humans. (World Health Organization 2006). The meeting gathered 72 participants, out of which 19 external experts, and resulted in the publication of the "WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment" on the WHO Web site on March 17, 2006 (World Health Organization 2006). Areas of work were largely diversified (more than 25 different areas of expertise) among external experts and WHO participants. It also shows a predominance of epidemiology (25%), followed by public health (8%), emergency action, and surveillance (4%). This meeting included experienced staff from WHO headquarters, regional, and country offices who specialized in operational planning, outbreak response, logistics, epidemiology, laboratory diagnosis, infection control, ethics, social mobilization, and public and media communications. Among the 19 external experts who attended this global technical meeting, there was also a predominance of epidemiology (26%), followed by logistics, occupational health, immunology and vaccines, and public health (all at 11%). These external experts had previous experience in containing infectious diseases, such as SARS or Ebola, represented institutions located in 12 countries from all continents and came from 17 different institutions, including universities, state agencies, agencies or programs of the United Nations (FAO, UNICEF, WFP and UNSIC), the International Federation of Red Cross and Red Crescent Societies (IFRC), centers for disease prevention and control (United States and Europe), one independent consultant, and one logistics experts from the Roche Group. The presence of a representative of the Roche Group was a completely new occurrence in such consultations. He was there to discuss drug stockpiling and distribution aspects after the Roche Group donated a stockpile of 3 million courses of oseltamivir (Tamiflu) to WHO to carry out the containment plan and dispatch these drugs at the source cluster (World Health Organization 2006).

The expertise for the preparation of this protocol was broad-based geographically, with a multi-disciplinary background in terms of the large variety of disciplines represented, as well as a diverse and international institutional representation. Financial, logistics, and legal fields were also represented but were not numerous, and all came from WHO. The field missions followed the same pattern. These missions were mostly jointly run by WHO and GOARN, and included representatives of the FAO and of the OIE when infection control measures and culling of animals was required, and with other institutions, such as the joint mission with the Asian Development Bank to Vietnam. Field missions were not only divers in terms of backgrounds of experts but also in terms of organizations represented. While more social sciences' aspects were included in the governance of avian influenza

compared to the analysis of SARS, expertise remained under-represented in the field of social sciences.

WHO formed its group of experts based mainly on the influenza network (as it was the case of SARS). This network was also a major provider for laboratory expertise. However, the organization of expertise had to comply with article 47 of revised IHR that prescribed the creation of a roster of experts in all relevant fields of expertise who should be appointed by the Director General in accordance with WHO Regulations for Expert Advisory Panels and Committees. In December 2008, only 56 experts were designated out of the 300 to 400 people to be appointed (World Health Organization - International Health Regulations 2008). In addition, an informal preliminary version of the emergency committee that was provided for in the revised IHR 2005 was set up to advise WHO leaders in decision-making. The exact composition of this committee was not disclosed but it included experts who are internationally recognized in the field. The constitution and the modalities of action of expertise were much more constrained in the avian influenza case compared to the SARS case, mainly due to the adoption of the revised IHR.

2.3.3. Process

The risk assessment process was organized around three poles: The observation and surveillance systems, the application of the risk assessment framework together with specifically designed protocols and the integration of latest research results into the risk assessment. While WHO played a central role in leading the SARS risk assessment, issuing a global alert, evaluating the risk level of affected areas and coordinating the international response, it shared risk assessment activities with other organizations such as OIE and FAO, had to coordinate the international response with the United Nations System Influenza Coordination (UNSIC) and financing institutions.

In the case of SARS, the rumors surveillance system captured initial information coming from unofficial sources that was analyzed by WHO and verified with authorities of the states concerned. The reluctance of the Chinese authorities to provide critical information (such as the identification of a new virus at the end of February 2003) and to allow experts teams to visit the Guangdong Province prevented the possibility of identifying the cause of the disease sooner. The identification process was biased by the false intuition about possible avian influenza cases, which probably delayed investigation of other possible sources of the disease. It was only after the disease had spread to Hong Kong and Vietnam that analyses became easier and similarities could be found and eventually traced back to Guangdong Province as well as the presence of a novel virus. The work of the Global Influenza network enabled the gathering of enough clinical and epidemiological information to warrant issuing the first global alert about a new infectious respiratory disease on March 12, 2003

that was followed by an emergency travel advisory of March 15, 2003. Then this network was supplemented by the establishment of three SARS-dedicated epidemiology, clinical management and virology networks that were instrumental in the risk assessment.

There was no specific standard protocol for the risk assessment of SARS. The risk assessment mechanisms applied by WHO included the application of its general risk assessment method, the decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern – the future Annex 2 of the revised IHR and the Guiding Principles for International Outbreak Alert to identify the risk source and to estimate the risk and the seriousness of its consequences. WHO used a combination of new mechanisms such as the networks of experts and the ground rounds, supported by modern technological tools like web-based technologies and video-conferences, with older mechanism like contact tracing also supported by such new technologies as electronic mapping.

The risk assessment mechanisms resulted in an estimation of the risk that was not expressed as a probability but rather as a scenario that took into account the disease characteristics, the virus characteristics once they became known, and the level of uncertainty. The case fatality ratio was raising, the disease was spreading internationally, affecting hospital staff in a higher proportion. Modeling studies were completed during the course of SARS with the first results published on line on May 23, 2003, by two teams; both gave a reproduction number estimated between 2 and 4 (as comparison influenza is around 10)(Lipsitch, Cohen et al. 2003; Riley, Fraser et al. 2003). In this analysis, actions to protect populations and to reduce uncertainty played a key role. The absence of knowledge at the initial stage was addressed by early decisions of standard precautionary measures such as isolation of patients and quarantine until the disease and its modes of transmission could be better known, which were expected in turn to help evaluate and potentially reduce the global impact of the disease. Subsequent discoveries such as the identification of the causative agent at the end of March 2003 reduced uncertainty and allowed for more targeted measures to reduce risk. However, uncertainty remained after the outbreak was declared over in July 2003. Research regarding the origin of the disease, its transmission modes, and its treatment has been undertaken, as has development of drugs and the tests for the production of a vaccine in the coming four years (Pearson, Clarke et al. 2003).

Following the alert, WHO implemented a procedure for daily reporting of probable cases, for which a standard format was provided to countries. Based on these data, WHO assessed the risk of epidemic and international spread, and classified countries by level of risk based on the pattern of local transmission (World Health Organization - Regional Office for the Western Pacific 2006, 69). For each

country in which an outbreak was verified and/or for each country that reported SARS cases, WHO assessed the local transmission level, assigned a rating, and published the list of affected areas on its website. A country would be rated as low, medium, high or uncertain. WHO's criteria for assessing the risk to international public health were the magnitude and the dynamics of an outbreak, including both the number of prevalent cases and the daily number of new cases; the extent of local chains of transmission; and evidence that travelers were becoming infected and were exporting the disease to other areas, possibly seeding an outbreak in those areas. Information reporting was crucial to the risk assessment, but difficult for WHO to obtain. China began to cooperate only late in the process, Thailand delayed information to avoid the impact in the tourism sector and Canada reported incomplete and incorrect information.

Unlike SARS, the alert regarding the resurgence of the H5N1 virus in February 2003 in Hong Kong was given through the normal routine surveillance activities of the WHO Global Influenza Surveillance Network. The two identified cases who traveled to South China remained a concern for Hong Kong authorities , based on the precedent of 1997. WHO followed up on outbreaks on a weekly basis or more if necessary. Officials in affected countries notified WHO of outbreaks (with the exception of Indonesia and reporting issues with Egypt). As virus analysis and development of vaccines was a central point of the preparedness activities, in 2004, WHO established the WHO H5 Reference Laboratory Network as an ad hoc component of the WHO Global Influenza Surveillance Network (GISN) (World Health Organization - Epidemic and Pandemic Alert and Response 2006).

The risk assessment was based on the same framework and principles as SARS. In addition, WHO used the pandemic phases risk assessment and declared the world to be in Phase 3 (World Health Organization - Epidemic and Pandemic Alert and Response). Phase 3 is characterized by human infection(s) with a new subtype, but no or very limited human-to-human transmission. WHO proceeded to a continuous risk assessment based on cases reporting, laboratory testing and field investigations in order to determine whether a new human virus appears and transmits easily among humans.

However, in terms of application of the overall risk assessment framework, the situation is different than SARS due to the fact that H5N1 avian influenza is a known disease for which the causative agent is identified and characterized. The cause-effect relationship is known as well as the lethal capacity of the virus. But controversies arose about the probability of the occurrence of a human influenza pandemic and the severity of its consequences. This debate and its outputs were critical, as the estimated number of deaths is a central element for preparedness activities. The position of WHO was that a pandemic was certain in the twenty first century, acknowledging as uncertainty the timing

of this pandemic and the virus (the source of the novel virus could be H5N1 or another virus). Modeling studies were used as a basis to produce different scenario, usually a mild and severe scenario (sometimes with a middle range scenario). WHO publicly communicated its first estimate of 2 to 7.4 million deaths that was based on the "mild" pandemic of 1968, to round it to 7 million in fall 2004 (Stöhr and Esveld 2004). However, experts such as Dr Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota considered WHO's estimate too cautious and responded that a 1918-like pandemic could kill at least 72 million (Enserink 2004). He published his conclusions about possible higher casualties ranging from 180 million to 360 million deaths in 2005 (Osterholm 2005). At the end of 2004, WHO published a statement recognizing the scientific grounds of the different estimates and providing a range of 2 to 50 million deaths, in which the 7 million deaths was presented as best-case scenario (World Health Organization - Epidemic and Pandemic Alert and Response 2004).

WHO justified the significant differences in estimates by the high level of uncertainty about the characteristics of the disease and the difficulties to make extrapolations from past pandemics. First, the proportion and the categories of the population that will be affected by the disease as well as the pathogenicity of the virus remain unknown. Second, the pandemics that were used as references for extrapolations presented different characteristics and incomplete or disputed data. Finally, extrapolations from past pandemics should take into account changes in the environment and the level of preparedness. As the level of uncertainty remains significant in regard to the risk of a human influenza pandemic, the risk assessment has been a continuous process based on global surveillance and work of experts who relied on the latest experimental and empirical studies aimed at increasing their knowledge about the current avian influenza virus H5N1, and in particular, about the different virus strains that circulated in the different countries, transmission modes, symptoms, clinical management, and effective treatments. In any case, WHO advocated for preparedness and referred to the mild World Bank scenario estimate of USD 800 billion per year (The World Bank - East Asia and Pacific Region 2005) as a justification to undertake costly actions for preparedness that could save future higher costs.

Risk analysis led to two types of measures: preparedness measures (pre-pandemic) and containment measures (pandemic). The first set of measures consisted of reducing the opportunities for infection in humans and increasing the preparedness level of member states and WHO by strengthening early warning systems and building up capacities to cope with a pandemic. WHO provided guidance on preparedness plans and public health measures, granted technical and financial support to less-developed countries, and worked on measures to contain any outbreak at its roots. WHO also

promoted the development of vaccines and the extension of vaccine manufacturing capacity as well as antiviral stockpiling. The second set of measures aimed at containing the disease at its roots or delaying its international spread, and reducing its casualties once a pandemic started. The containment protocol consisted of a roadmap to prepare WHO and its partners to intervene quickly once the pandemic risk materialized.

3. Conclusions

One new and key feature of the SARS risk analysis was the constitution, the organization, and the role of expertise. For the first time in its history, WHO set up and coordinated virtual networks of virology, clinical, and epidemiology experts in a continuous real-time cooperative risk assessment. This science-based risk assessment process was meant to be a privileged interface for the exchange of information, research findings, and ideas in order to design and implement the most easily adapted measures. This innovative risk governance mechanism was instrumental in discovering the causal agent, monitoring the clinical course of the disease, and providing epidemiological information to refine the recommended measures. This cooperation was overall a success, which should not minimize the challenge it represented in terms of managing different agendas, priorities, and competition in a race to publish findings and the characteristics of the virus itself.

With SARS, WHO took the lead and the responsibility in assessing and managing risk in an emergency situation of global scope. During the few years preceding the SARS outbreak, WHO had been increasingly involved in managing outbreaks in different parts of the world, suggesting that its role was changing towards coordination of global risk governance processes in addition to the conduct of long-term public health programs. The SARS outbreak consisted of the first real test of this new global role. It was a learning experience in global risk governance that was followed by the integration of the lessons learned into the strengthening of the risk-based approach to prepare for future outbreaks. WHO'S legitimacy to conduct that risk governance process was recognized by states and other actors. From a state perspective, implementation of new practices preceded the formal approval of the rules and the documentation of risk assessment plans and mechanisms, resulting in an action-based legitimacy rather than a rule-based legitimacy. The revision of the International Health Regulations had already been launched, and if WHO's actions were inspired by the 2002 project, these measures had not been approved by member states prior to their application. States could have opposed WHO by refusing to cooperate and report cases, by trying to form coalitions to block the resolution that was proposed at the World Health Assembly, or by launching a media campaign denying the legitimacy of the organization to act. The situation was not without issues, such as the Chinese's initial reluctance to cooperate or the reaction of Canada against

travel restrictions, but overall, the recommendations of WHO were applied. However, in response to the WHO's increased role, states included a consultation phase before the issuance of an alert as part of the revised IHR 2005, revealing the willingness of states to keep some hand on the management of health issues.

In the midst of the SARS outbreak, cases of avian influenza among humans were confirmed in Hong Kong in February 2003. This announcement caused WHO to suspect that the outbreak that the Asian countries and Canada were facing might be of an avian influenza origin. This assumption would eventually be ruled out and WHO had to deal with two different risks in parallel: SARS and a human influenza pandemic, the latter benefiting from the lessons learned in dealing with the former.

WHO carried out a risk assessment in order to anticipate and prepare for a human influenza pandemic. The risk of a human influenza pandemic that could originate in the H5N1 avian virus has not materialized, as the current H5N1 human virus does not transmit easily among humans. This virus, which caused the death of numerous animals and of a limited number of humans, was known from a previous outbreak in Hong Kong in 1997 to be a virulent and highly lethal virus. Experts feared that it could transform into a malignant form easily transmissible between humans, causing a pandemic resulting in a high rate of death and significant economic and social costs worldwide. The characteristics of the virus and the fact that humans caught the animal disease were the first indicators of a pandemic risk, and led to the declaration of phase 3 in the pandemic scale established by WHO. In 2005, the predictions were alarmist as this pandemic was compared to the Spanish Influenza, initiating a dispute among experts about its potential significant consequences in human losses ranging from 2 million deaths to more than 300 million on a worldwide basis with cost estimates ranging from USD 200 billion to USD 4 trillion depending on the parameters and assumptions used in the models. WHO led a risk assessment to estimate the risk of such a pandemic, its potential impact and the measures that could be taken in terms of one scenario. If the H5N1 virus did not cause the pandemic, another virus would; therefore, preparedness was key and would serve in any type of pandemic or a biological accident. While experts disagreed about the probability of occurrence of a pandemic, they agreed about the severity of its consequences (but not about its magnitude).

As research is key in pre-pandemic and pandemic activities, WHO organized an international, multidisciplinary, and institutionally broad-based expertise to plan, carry out, and integrate research results into the risk assessment. WHO organized multi-stakeholder technical meetings and international conferences about the animal and human sides of the disease as well as funding

operations to be assessed comprehensively to target the responses, gather the competencies, and secure commitments to achieve the response.

WHO's strategy was based both on an action-based and rule-based legitimacy as the adoption and the entry into force of the revised IHR 2005 occurred during the formation of the response. The IHR 2005 was a compromise between WHO's practice in the SARS case and states' concerns about their sovereignty, which resulted in the integration of a consultation phase with the affected state or states before raising a global alert. The concept of public health emergencies of international concern was validated and coexists with a list of diseases that require notification. The IHR 2005 provided WHO and states with a binding international instrument to handle infectious diseases, including a standard risk assessment plan in its Annex II, focal points to ensure coordination, and an emergency committee consisting of multidisciplinary and internationally recognized experts. The IHR 2005 does not plan for coercive sanctions but rather operates on a credibility-based and notification-assistance incentive system.

WHO learned from the SARS experience in terms of organization of expertise, conduct of operations, and communication and consolidated its global coordinating role of risk assessment and risk management at the international level. Coordination was challenging as it involved more partners due to the multiple facets of the issue and the different initiatives launched in the fields of animal and human health. WHO moved toward a multi-stakeholder process both for the risk assessment and the completion of the response. For example, preparedness activities could essentially be funded by the pledges administered by the World Bank. The time factor played a role, however, as the disease in animals could be detected and its opportunities to infect humans potentially reduced by animal-culling campaigns and implementation of infection control measures. As time passed, the commitment to preparedness actions declined and questions were raised about the cost-effectiveness of pandemic preparation as the risk of a pandemic of avian influenza origin did not materialize.

WHO positioned itself as a central player in the global governance of the SARS crisis and as an active player in the avian influenza H5N1 pandemic. Over the past ten years, the WHO has developed surveillance systems, revised the IHR and reinforced its risk assessment mechanisms. WHO has been increasingly involved in preparedness against and containment of epidemics, which set bases for its prominent – and contested - role in the risk analysis of the H1N1 pandemic in 2009. In fact, some segments of civil society have challenged the position of the organization by advancing three main arguments: the organization's dependence vis-à-vis pharmaceutical companies, the overuse of precaution and the exaggeration of costs. While the external reviewers did not find evidence of

influence, they proposed amendments to the IHR and risk assessment mechanisms. WHO thus retains significant capacities in terms of assets, skills and capabilities to govern pandemic risks. However, the organization's legitimacy has been impaired, challenging its positioning as a leading actor in the governance of pandemics, at least in the near future.

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