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Thinking the International Response to a Global Health Risk

This chapter provides the theoretical basis for the empirical casework that follows. It firstly draws on the definitions of key concepts and theoretical elements presented in the literature review to provide the analytical framework on which this research is based. It then provides an overview of the process and key dimensions of the analysis of risk and the formation of an international response to it. It ends with a brief description of our approach.

Our framework is original in the sense that it introduces additional elements such as the notion of legitimate basis for the action of the multilateral institution and the existence of a risk assessment method, and it focuses on the existing and newly established risk assessment mechanisms and combines scientific risk assessment techniques with economics-based tools such as cost analysis in order to reach a more comprehensive approach. The combination of these elements allows for an evaluation of the quality of the risk analysis and, in turn, to determine whether these elements contribute to the quality of the response. Our framework borrows elements from both the technical approach to risk (in particular from the Red Book risk analysis framework) and business risk management techniques commonly used in companies, which consist of reducing uncertainty in order to understand more precisely and estimate the risk, thus allowing for more targeted action. In particular, the procedure of hazard identification, dose-response assessment, and exposure and risk characterization was used as guidance to analyze the activities of multilateral institutions, along with cost analysis, monitoring, evaluation of implementation problems, continuous improvement, and iterative characteristics of the business risk management process.

N. Brender, *Global Risk Governance in Health*

At a specific moment in time, one actor issues a risk warning. This actor may be an inside or outside agent of the multilateral institution, and its warning may or may not be revealed in the media.[1] For the purpose of our study, we consider this warning that is captured by the multilateral institution as the triggering fact for the risk analysis process. This warning initiates the performance, within a multilateral institution, of a risk analysis in order to identify and evaluate the risk. The actors who participate in the risk analysis process, in identifying and evaluating the potential risk drivers and risk consequences, feed the risk analysis process with their theoretical and empirical knowledge. Risk analysis is based on a method, and it may take the form of an institutionalized, structured, and formalized process with predefined procedures, milestones, and requirements, or it may consist of a more informal and participative forum. Risk-related activities of multilateral institutions should appear legitimate to its members, thus relying on a formal agreement or recognition of action. The multilateral institution uses existing or establishes new risk analysis mechanisms in order to complete the risk assessment.

The process will result in a quantitative or qualitative estimation of the risk, or a combination of both, and a proposal of measures to be taken to reduce the risk. The appropriateness of this response that is provided by the multilateral institution will depend on the existence and the quality of the risk analysis performance. This response is designed to ensure the highest level of preservation of collective interest or, in other words, the highest level of risk reduction based on the information available at the time of the decision. The risk reduction level will translate into lower casualties in terms of impact on human lives, on other countries, and with respect to economic costs. This response should be the result of consultations that are formalized (documented), publicly communicated, and implemented. The implementation of the response is based on mechanisms that are internal and external to the multilateral institutions. While the multilateral institutions ensure the compilation and communication of information, regular reassessment of the issue and monitoring of the implementation of the response states are instrumental in reporting information to the multilateral institution and carrying out the measures that are recommended. Other actors such as nongovernmental organizations (NGOs) or private companies can also contribute to the completion of the response.

The monitoring of the response's implementation is a key element of the risk management process. Risk analysis is not linear, with a beginning (a risk) and an end (a solution to that risk). It is, rather, a continuous process of regular reassessment of the situation, the potential

consequences, and the validity of the measures adopted in light of any new information acquired by the scientists and professionals dealing with that particular risk. Global risks often are characterized by uncertainty due to a lack of knowledge about the likelihood of occurrence of an event (e.g., the probability of a human influenza pandemic), its magnitude or damage (e.g., the number of persons infected and the number of deaths, as well as economic costs), its initial location, and its timing (where it could arise and when). Information about these elements may evolve over time and result in reviews of the previously adopted measures. These measures can be confirmed, modified, or canceled depending on the results of this continuous risk analysis.

The level of knowledge is not the only element driving this process. The success or the failure of an international response is another aspect of the continuous process. An evaluation of the response (whether the measures were applied and how effectively they were applied) should be performed to determine whether the objectives set have been met, not met, or partially met, and why. Measures that are not implemented or are partially implemented may be a sign that they are not accepted or understood by the concerned populations, are too costly, or are not adequate for the situation. The outputs of this evaluation should be used to feed the risk analysis process so as to continue to analyze the risk and formulate new responses. This continuous and iterative process can be illustrated as follows:

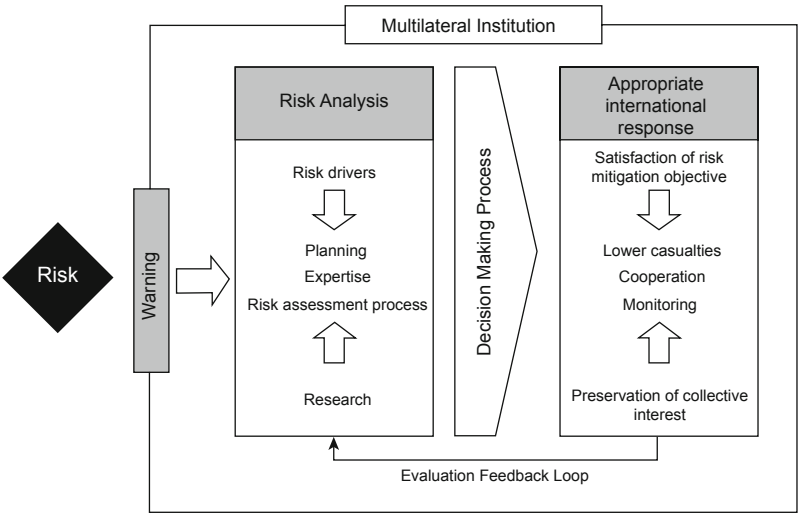

Figure 1.1 Iterative risk analysis process

1.1 Analyzing risk

Within this framework, risk analysis is based on the scientific assessment of an issue that ultimately aims to gain more knowledge about the issue and reduce uncertainties (whenever possible), including conducting a cost analysis and benefiting from the multilateral institution's legitimacy of action. Risk analysis, for the purposes of this study, is defined as *an expert-based deliberative and participative process that takes place within or under the lead of a multilateral institution, consisting of the performance of a scientific assessment of the risk according to a predefined plan or an organized method and addresses possible risk sources and their potential consequences* and is characterized by three key dimensions: planning, expertise, and the risk assessment process. We will use these dimensions as key milestones to analyze each empirical case.

First, the *planning* dimension provides for the general conditions under which risk analysis can take place. It is composed of a predefined plan or an organized method, and rests on a legitimate basis for the multilateral institution's action. The *method* that is used as the basis for the risk analysis can take the form of a conceptual formalized model (a predefined and documented risk analysis method, model, structures, and processes) or an empirical (and informal) method. This plan is built to track the risk, identify its source(s), and establish a risk causal chain. It can be inspired from existing frameworks such as the American National Research Council risk analysis framework (the Red Book risk analysis framework) or specifically designed for an institution. It also includes conventions and procedural rules, in particular addressing how to estimate the risk and accounting for uncertainties. (2 p. 13) The integration of lessons learned from past experience or from similar cases (if available) and the link to the potential consequences of the risk materialization can also be part of this method. The concrete application of this method should serve in conducting the risk assessment process. Examining the steps of the risk analysis process also can provide indications of the method applied, as well as oral comments about the risk analysis performance.

The *legitimate basis* for risk analysis under a multilateral institution refers to the notion of legitimacy, which gives rise to different interpretations in the literature. The legitimacy of an institution in its normative sense refers to the right to rule, and in its sociological sense to the belief in the right to rule. (22 p. 405) Multilateral institutions historically have derived their right to rule from international agreements.

States delegate certain competences to the organization to issue rules and to ensure their compliance by the parties to these regulations. The IHR are an example of such agreements that confer rights to the WHO to use nonofficial sources to detect disease outbreaks and to issue recommendations to handle them. The European treaties also confer rights to the EU to issue regulations in specific areas, and the European Court of Justice represents one instrument of compliance available to the institution to ensure compliance with the European regulations. This 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 matters as well.

Believing that an institution is legitimate is an essential element in supporting its actions. Legally accepted bases for action are a necessary but insufficient condition of legitimacy. Formal legitimacy may be ineffective if no broad-based support from the public is associated with it. Keohane and Buchanan combine normative and sociological aspects to define legitimacy as "the right to rule, understood to mean both that institutional agents are morally justified in making rules and attempting to secure compliance with them and that people subject to those rules have moral, content-independent reasons to follow them and/or avoid interfering with others' compliance with them." (22 p. 411) We share with these authors the idea that formal delegation of competences granted to an organization is a necessary but insufficient condition for legitimacy. But focus remains the multilateral institution and the support granted to its action by member states, as states are considered the primary partners of the multilateral institution in implementing the response to a global risk, and stakeholders' concerns are not analyzed here. Legitimacy essentially will be derived from the application and compliance by the states to the measures adopted by the multilateral institution.

Our approach considers both "rule-based" and "action-based" legitimacy. Legitimate bases for action are derived from two nonexclusive sources: the multilateral institution's constitutive agreement (e.g., treaty or constitution), regulations, or rules accepted by member states, and generally accepted practices within a multilateral institution. For example, certain WHO practices in response to the Severe Acute Respiratory Syndrome (SARS) outbreak, such as the use of nonofficial sources of information, generally were accepted by member states, although they were formally accepted as rules by the World Health Assembly later in the process, and then in the revised IHR in 2005.

Second, the *expertise* dimension combines the requirements for a diversified and internationally recognized background of the expertise involved in risk analysis, as well as the integration of the latest research, results in the risk estimation and proposition of measures. The *background* refers to the quality of scientific expertise involved in risk analysis, including the best-available scientific knowledge. There is no agreed-upon definition of expertise, but it seems generally accepted at the international level that it should be multidisciplinary and highly qualified in order to ensure that the best-available and more comprehensive scientific knowledge is used in a balanced way to analyze risk and propose measures. International expertise can be analyzed through excellence in performance or based on nomination. An expert is considered to be a skilled performer and recognized as an expert in his/her field. This recognition is based on several dimensions, including education, practical experience, and organizational role (23 p. 602).

In our approach, the quality of expertise is determined by its *background diversity*, which is defined by multidisciplinary, institutional, and geographical broad-based origin and an international track record. The combination of theoretical knowledge, knowledge of risk approaches (quantitative assessment and qualitative assessment such as scenario techniques), and past experience gained in different disciplines is considered to enrich risk analysis. For example, teams may be composed of individuals who are active worldwide in research institutions, universities, or laboratories, high-level professionals with field practical experience, internal expert officers working for the multilateral institution, and experts from other organizations. The review of the professional background, the institution of origin, and the country, as well as the level of experience of the key participants involved in the risk analysis process, will be based on public documents such as lists of participants, minutes, and reports regarding specific risk analysis meetings, complemented by interviews. The international track record of participants can be derived from the estimation for the group of the quantity and quality of international publications in peer reviews.

The *research* part of the expertise dimension is dedicated to the capacity of the multilateral institution to obtain and integrate the latest research results available into the response. It is important that the risk analysis encompasses the most recent research developments, particularly in the case of situations of uncertainty, when knowledge about the risk is progressing regarding the origin of the disease, its symptoms, its transmissibility, and its clinical course. Research findings can contribute to a more precise risk assessment that in turn may result in more targeted

and effective measures. Evidence on how research is conducted to reduce uncertainty, the publication of results, and the integration of these results in recommendations can be found in meeting minutes, press releases, public communications, and documents of multilateral institutions and secondary sources that have analyzed the cases under study, as well as interviews. When available, it is also interesting to consider which resources were allocated to research and how they were split among the participants, when, and for which results.

Third, the *risk assessment process* dimension is composed of a series of steps that lead to the risk estimation and proposed risk management measures combining scientific assessment and cost analysis techniques. We consider the presence of an observation system, risk analysis mechanisms, and cost analysis as essential components of this process. The risk assessment process relies on the presence of a continuous *observation system* that reports information on a regular basis about risk issues that serve as a basis for the risk analysis. This system may report a warning concerning a potential risk or a new risk, and the development of that risk. This observation system (also called surveillance system) can be human or system based, or both. It may encompass different mechanisms and tools in order to achieve its mission of providing information. For example, it can take the form of computerized surveillance systems that compile facts reported in a particular field (such as disease outbreaks), human activities of observation in the field, or an international forum for professionals who exchange knowledge about a particular issue. This observation system can be internal or external to the multilateral institution, or a combination of both. The Global Public Health Intelligence Network (GPHIN), which represents one element of the WHO observation system, provides this organization with information about disease outbreaks that occur worldwide.

Risk assessment mechanisms mainly relate to how risk analysis is performed in terms of activities, resources, and tools. Risk analysis mechanisms consist of activities carried out to identify the risk source(s) and evaluate the relationship between the risk source(s) and the potential consequences of the risk, including the determination and exposure of the populations at risk. These activities should result in an estimation of the probability of occurrence and the seriousness of the consequences of the risk, a communication of uncertainties, and a proposal of measures to reduce the risk. The mechanisms are often contained in the risk analysis method, but can also be a current practice that is not documented. They also can be adapted or customized upon the identification of a new risk. Risk assessment mechanisms are mainly science based and

may operate using different tools such as modern telecommunications or top-level research infrastructures.

In our analysis, risk assessment mechanisms are essentially science based and borrow elements from the technical risk framework, as well as the American National Research Council risk analysis framework. Based on the latter framework, WHO defines risk assessment as "the process of evaluating the probability and consequences of injury or illness arising from exposure to identified hazards," hazard being the potential to cause harm and risk being the likelihood (or probability) of harm or damage occurring from exposure to a hazard, as well as the possible consequences. (24 p. 10) Based on this definition, WHO would carry out three main steps: identification of the source, vulnerability assessment, and estimation of the consequences. In practice, risk assessment mechanisms include risk-tracking or risk-tracing activities to determine the cause(s) of the risk (the hazard) by investigating different presumptions or intuitions based on the available knowledge about the issue at a particular time.

Proceeding to a risk assessment can be particularly difficult in situations that present a high level of uncertainty, as risk characteristics may be completely unknown or partially unknown. One challenge of any risk assessment process is to take into account the fact that knowledge about a particular risk is still in construction. When the level of uncertainty is complete or remains high, the technical approach to risk shows certain limits. The absence of sufficient and relevant historical data, as well as the gaps in knowledge to confirm the causal relationship between the hazard and the risk may prevent the calculation of a relevant probability of occurrence and the estimation of the consequences. Instead of quantitative mechanisms, more qualitative mechanisms are applied to combine elements of developing risk knowledge such as experimental or empirical references, analogy thinking, integration of lessons learned from past experience, and formulation of best estimates of probabilities and damages or use of scenario-building techniques. However, one should be aware that psychology judgment biases such as availability, anchoring and adjustment, representativeness, and overconfidence may influence the judgment of experts with respect to risk and the estimation of its probability (25 p. 111).

The scenario technique consists of "thinking about every scenario possible and its consequences". In most cases, the assessment proposes three scenarios: a best-, a middle range-, and a worst-case scenario. As risk assessment is a continuous process, the experts can revise their assessment based on the latest experimental and/or empirical studies, aiming

at increasing knowledge about the risk and establishing a link between one or a few risk source(s) and the risk under study. For example, the risk of an influenza pandemic has been analyzed on a national basis, taking into consideration different scenarios that are mainly based on different estimations of the percentage of the population affected and the number of deaths estimated in order to evaluate the burden on health care resources, as well as the potential socially disruptive impacts. Computerized models using parameters from previous pandemics have supported these evaluations in order to produce quantitative figures, although the virus is not yet known. Official documents published by the multilateral institutions, such as the existence of references to or documented scenarios, risk estimates or risk-related information such as documented risk cartography, lists of risk drivers or risk sources, and analysis of their possible consequences provide information about the concept and practices of risk assessment mechanisms. Findings communicated by the experts (e.g., communications, recommendations, reports) who perform the risk analysis and have published studies (e.g., articles in peer reviewed journals) are valuable sources of information as well.

The risk assessment process entails a *cost analysis*, which refers to cost-benefit analysis that is commonly performed in the business sector to determine the most profitable option. However, cost-benefit analysis cannot systematically be performed, as cost considerations may be prohibited by law (25 p. 84) (e.g., safety regulations) or be considered unethical when dealing with risks in which human lives are at stake, such as health and food safety risks. (6 p. 18) In addition, concerns also have been raised with respect to the fact that cost-benefit analysis could dominate the debate and the decision-making process to the detriment of exchanges about conflicting values regarding the risk. (25 p. 104) However, some sort of cost-benefit analysis is a complement to informed decision-making about risk, but can take different forms according to the risk fields, as the EU recognizes in its impact assessment guidelines.

This cost-benefit analysis often is replaced by cost-effectiveness analysis in order to evaluate and compare the relative costs and effects of two or more measures. For example, WHO has developed the approach CHOICE (CHOosing Interventions that are Cost-Effective) to evaluate and compare the costs and effects of an intervention with the burden that would exist in the absence of that intervention. (26 p. 12) This method is often referred to as "cost-effectiveness analysis" (CEA) (27, 28) and results in the calculation of a cost-effectiveness ratio. This ratio is taken into account in the decision made on the implementation

of measures to deal with a specific risk and can be compared to the ratios of other programs. However, this approach requires a large number of available data and is time consuming and difficult to communicate. (28 p. 241) In addition, although the level of uncertainty has been reduced in the model, it cannot be eliminated.

Although this cost-effectiveness analysis cannot be applied as such to global risks in which the level of uncertainty remains high, insufficient data are available, and time pressure is growing, the performance of some sort of cost analysis is a key element of the risk analysis. The proposed measures that result from the risk assessment process represent costly actions that must be undertaken upfront in order to become prepared to deal with the risk if it materializes. These upfront measures are expected to enable more costly future actions to be avoided that will have to be taken in an emergency without prior preparation once the risk materializes. The costs to be incurred in the present time should lead to the avoidance of higher future costs, considering that these measures would reduce the risk. This cost-saving relationship depends on the probability of occurrence of the risk and the discount rate used to evaluate the future costs. (6 p. 18) This cost-saving relationship can be expressed in monetary terms and nonmonetary terms, such as human lives saved, in official documents, press communications or articles.

1.2 Responding to risk

The combination of legitimacy and the capacities of the organization and the quality of this analysis is expected to influence the quality of the international response to risk through the implementation of measures that increase net benefits to human societies by preventing or reducing harm to humans and the things they value. In that context, the appropriate international response shall be understood as *a concerted, formalized, and publicly communicated risk reduction measures that aim to ensure the highest level of preservation of collective interest and that are adopted and implemented in a cooperative manner, as well as continuously monitored*.

First, the dimension *lower casualties* refers to the reduction of the consequences. The multilateral institution's response contributes to the supply of risk reduction (that can be considered as a global public good), which ensures the preservation of the collective interest on a worldwide basis. The preservation of collective interest raises the question of a society's acceptable level of risk. Reducing risks (for example, limiting the severity of consequences) entails costs as well as benefits. In most cases, it is reasonably stated that there may be an optimal level of

risk at which costs and benefits are in balance. However, there may be too much uncertainty to evaluate these costs and benefits with a sufficient degree of confidence as is the case for emerging pandemics such as SARS or influenza. Alternatively, disagreements may arise regarding the threshold to be applied to determine the acceptable level of risk.

The acceptable level of risk is often defined by a technical threshold that triggers specific actions, or by balancing the cost-benefits of variable options, or through cooperation in accepting a risk level. First, a technical threshold in terms of costs and benefits is difficult to apply to health-related issues for ethical and social considerations. (4 p. 261) For example, WHO does not apply thresholds that are expressed in terms of acceptable cost of human life; rather, it uses thresholds stated in absolute terms, such as preventing a pandemic from occurring or reaching a flu-free world (or a SARS-free world), and therefore promotes containment and eradication measures to manage these diseases. Second, balancing the cost-benefits of variable options with a sufficient degree of confidence remains difficult in situations that involve a high level of uncertainty. This approach has been partially adopted by WHO in long-term health programs, but not for emerging pandemics such as SARS or influenza in which estimates may vary significantly. Third, cooperation in accepting risk level necessitates the inclusion of stakeholders. Thresholds are the result of negotiations and are reviewed periodically, which is more practical at local or national rather than global levels. For these reasons, we focused on casualties as an indicator of the preservation of collective interest that would express how the multilateral institution performs in providing measures to reduce the risk or eliminate it. A decrease in casualties following the implementation of proposed measures would be interpreted as a sign that the containment and eradication of the disease are progressing. This decrease in casualties contributes to preserving the collective interest by reducing the occurrence and/or the severity of consequences of the risk.

Lower casualties can be evidenced by three indicators: spread, impact on human lives, and economic cost. First, *spread* can be evaluated by the number of new countries affected by the risk event (e.g., a disease). In practice, the preservation of the worldwide collective interest if a new infectious disease emerges could be expressed in terms of the geographical spread of the disease by recording and comparing the number of new countries affected by the disease since the alert was given, until the measures were implemented; or after the measures were taken up, until the first deadline set for an evaluation of these measures; or up to the stage at which no more new countries are affected. The evolution of the

spread can be derived from reported data published on the websites of the multilateral institutions. Risk reduction is considered to be achieved when there are no new countries affected, and when countries affected can be declared progressively risk free.

In addition, the impact on human lives can be measured by the evolution of the *number of cases* and/or case fatalities. These data often are published by the multilateral institution based on reporting from the member states. When sufficient and relevant data are available, the mortality rate[2] and the case fatality ratio[3] also could be used as measures of the impact on human lives. A decrease in the number of additional cases and a decline in the epidemiological curve (total number of cases) are considered to be risk reduction. The indicator of the reproduction[4] number R_0 often is used as a metric to evaluate the spread of a disease among a population. When R_0 falls below 1, the epidemic is considered to be contained. The international geographical spread and the evolution of cases among populations are both necessary in order to evaluate the level of casualties. A disease with a high R_0 may result in a large number of cases localized in one specific area and no international geographical spread due to the implementation of rapid and effective containment measures. In contrast, a disease with a low R_0 still could spread to a lot of countries and result in a significant number of cases over time, although it may not result in high numbers of cases locally.

Finally, the actual *economic cost* of the actions taken can be compared to the planned cost and/or the cost of inaction. Economic cost sometimes also is compared to that of previous similar events in order to evaluate the impact of the different measures taken to determine the most cost-effective ones. For example, a simulation using the Monte Carlo model estimated the economic impact of a pandemic in the United States of between USD 71.3 and USD 166.5 billion, excluding disruptions to commerce and society, and projects' net savings or losses, depending on the price of the vaccine and the number of persons vaccinated. (30) These cost comparisons between the vaccination and the lack of vaccination are based on computerized computations, taking into account different parameters. These indicators often are produced by computerized mathematical models. The scenario analysis may also provide a basis for comparison between the worst-case scenario (e.g., the risk materializes and no prior action was taken) and the costs of measures proposed to prepare for the risk for a medium- or best-case scenario.

Second, the *cooperation* dimension relates to the way in which decisions are made. To a certain extent, it can be extended to the relationships with other organizations when the design and implementation

of the response require the contributions of different – and sometimes competing – international organizations. The decisions with respect to risk reduction measures are the result of a dialogue (consultation process), are reached by consensus (collegial decision), and are publicly communicated (public decision). These decisions are sometimes expressed as deliberative or participative processes and considered an interactive and mutual learning process, resulting in a more democratic decision.[5] The group of experts mandated by the multilateral institution to perform the risk analysis decides collegially with respect to the risk reduction measures that will then be proposed to the multilateral institution's top management for adoption. The decision is the action of a group, not one individual. These measures are the result of a consultation process and are publicly communicated, generally on the institution's website. Such a process reinforces the binding effect of the decisions: the actors have the opportunity to address the issues and to defend their propositions and solutions (the dialogue phase); they are involved in the decision-making process (each voice has its importance); and the decisions are publicly communicated (every actor has access to the same final information). Cooperation is said to improve communication by allowing exchanges of information, the creation and reinforcement of confidence, conflict resolution, and training with respect to the risk (6 p. 203).

The existence and performance of a *consultation process* shows the presence of a dialogue. Consultation processes can take the form of general or technical meetings dedicated to the risk analysis. The consultation process is supported by the multilateral institution's general rules and procedures, and the evidence of its presence can be derived from official documents, such as the minutes of these meetings or the regulations, guidelines, or procedures issued as a result of these meetings. Such documents often describe the themes that were discussed and the manner in which the decision was reached. Information from interviews can complement the analysis.

The *collegiality of the decision*, the fact that the decision is a group decision and not that of one individual, can be attested by documents showing that the group has been working on the issue and that this discussion resulted in the production of a common document to which everyone agrees. It also can be based on the multilateral institution's bylaws or procedures stating the decision-making rules (e.g., a decision made by an assembly or a committee).

The *public communication* of the decision can be verified by analyzing measures posted on the institution's website, press releases published, or information disseminated by the media.

Third, the *monitoring* dimension of the response refers to the follow-up with respect to the implementation of the measures and their evaluation. A *reporting system* is established to track on the implementation of the measures adopted regarding the risk that was tackled. This reporting system is administered by the multilateral institution, but different sources provide the system with information. These sources include the institution itself, state authorities, stakeholders, and laboratories for health-related issues. Conclusions about the effectiveness of this reporting system can be derived from the analysis of the information it publishes.

In addition, an *evaluation of completion* of the measures adopted represents also a key element of the international response monitoring. This evaluation can consist of self-assessment reports of the entity concerned or of an external evaluation of the measures implemented. For example, the multilateral institution can carry out evaluation missions with a selected team of experts, obtain audit reports, or receive oral or written communications about different actors involved in the process (state parties, NGOs, etc.). Field mission reports, self-assessment reports, and a multilateral institution's communications, as well as dissemination of information from other sources such as the media or NGOs are the privileged information providers for analyzing whether countries applied the proposed measures.

Finally, *enforcement tools* refer to the capacity of the organization to have the measures complied with. This is a complex aspect, as multilateral institutions may issue recommendations that do not have a legally binding character and with which no penalties can be associated in monetary terms. For example, an agreement such as the IHR is self-enforcing and based on the good will of its state parties. Enforcement mechanisms can be prescribed in legally binding documents such as the bylaws, the constitution, or specific regulations, but they also can be based on informal means such as generally perceived incentives to cooperate, for example to maintain, restore, or improve international reputation and credibility.

Multilateral institutions can be confronted with not only free-rider problems but also moral hazard issues. Moral hazard is a notion from the insurance field whereby the expected payout for a loss unintentionally encourages excessively risky or fraudulent behavior. (31 p. 219) More generally, one actor may act less carefully (or even fraudulently) considering the fact that another actor is taking the responsibility for the consequences of the actions of the first actor. For example, countries

may not declare an outbreak of an infectious disease (or deny the existence of such an outbreak) and take no preliminary precautionary measures such as infection control measures and social distancing measures, knowing that WHO will identify the disease, send expert teams to the field, and organize the response globally. Such behavior may jeopardize the ability to contain the disease worldwide, and WHO has to find strategies to encourage the cooperative behavior of states. Strategies of cost sharing, randomization, and regulation have been applied in the insurance sector and expressed in monetary terms. (31 pp. 227–232) Transposed to a context of global risk, the strategies may be difficult to carry out, in addition to the fact that units of measurement may be different. Cost sharing between the careless actor and the multilateral institution is difficult to establish when no monetary penalties have been established upfront for such behavior. In the case of WHO, it could implement strategies such as withholding assistance interventions. However, these actions, while targeting a state behavior, may have negative consequences not only for the population of this state but for other populations as well. Randomization consists of adding uncertainty about payouts to reduce risky behavior. Again, this strategy would be difficult due to the already high level of uncertainty existing in global risk situations, and vagueness about a possible intervention would make a difficult difference within that context. It also would increase exposure of the population to the risk. Finally, regulations can be established to limit the payout to the actors that behave responsibly. Although regulations provide expected rules about behavior, if these rules have not been agreed upon upfront, such strategies are difficult to put in place. For example, the IHR do not prescribe penalties for states that fail to report outbreaks. Therefore, WHO could, with difficulty, grant assistance only to countries that report outbreaks and leave unattended countries that do not.

Therefore, incentive-based strategies appear to be more powerful tools than coercive strategies and provide additional enforcement leverage for the institutional frame of regulations to foster cooperative behavior. For example, in accordance with the IHR, the fact that WHO will know about outbreaks from nonofficial sources of information may influence states positively to spontaneously report them in order to benefit from direct consultation before any public communication and early assistance. In addition, the incentive of confidence-gain or confidence-loss may be strong in an interdependent world in which reactions can be immediate in a response to a behavior that is considered deviant from the norm.

Stopping trade relationships could have important repercussions, and it might be beneficial to avoid them through immediate collaboration.

The process of thinking the international response can be represented in the figure below, which summarizes the key features of the risk analysis and the formation of an international response to a global risk:

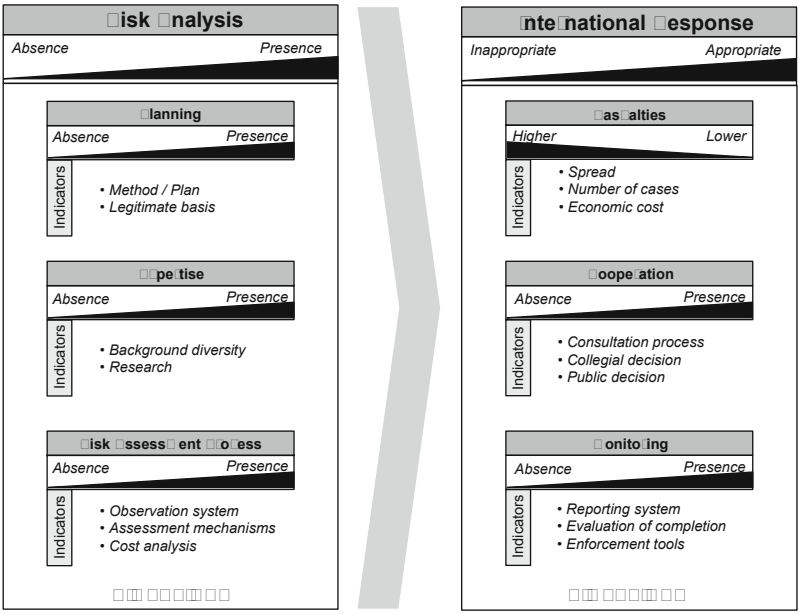

Figure 1.2 Thinking the international response

These dimensions were applied as pillars to organize our analysis of the selected empirical case studies in the field of health addressed by WHO. The absence of one dimension, be it planning, expertise, or the risk assessment process challenges the presence of risk analysis. Risk analysis depends on the legitimacy and methodology, on the work of the experts, and on risk assessment mechanisms developed to address the risk. The same is true for the international response. An appropriate international response includes cooperation and response monitoring and results in lower casualties. The first case addresses WHO's guidelines with respect to SARS and the recommendations issued by WHO from February 26, 2003 (date of the first reported emergence of the

disease in Hanoi, Vietnam), to July 5, 2003 (WHO announcement that the last human chain of transmission was broken). And the second case analyzes WHO's preparedness activities for facing a risk of human influenza pandemic that could arise from the avian influenza H5N1 outbreaks from February 19, 2003, to December 31, 2008. These cases were analyzed using a qualitative approach based on content analysis of documentation – mainly primary sources – and interviews of actors and researchers.