

## LEGAL BOUNDARIES PREPAREDNESS AND CONTROL IN HEALTH AND BIOLOGICAL HAZARD RISK PLAN (HBHRP)

### PREPARAÇÃO E CONTROLE DOS LIMITES LEGAIS NO PLANO DE RISCO À SAÚDE E RISCO BIOLÓGICO (HBHRP)

### PREPARACIÓN Y CONTROL DE LOS LÍMITES LEGALES EN EL PLAN DE RIESGO PARA LA SALUD Y RIESGO BIOLÓGICO (HBHRP)



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#### ABSTRACT

This chapter emphasizes legal boundaries and national ethical frameworks when public administration develops Health and Biological Hazard Risk Plans (HBHRP). The chapter emphasizes establishing a coordinated framework for strategies, preparedness, and control, particularly before making decisions and managing public health risks. The discussion focuses on international orientations like the Global Health Security Agenda (GHSA), World Health Organization (WHO), and International Development Law Organization (IDLO), which suggest guidelines for enhancing a country's capacity to prevent, detect, and respond to infectious disease outbreaks. International orientation addresses developing nations and less for countries participating in GHSA's exercises. The European Privacy Regulation (GDPR) is an example to explain potential legal conflicts. The chapter examines conflicts between private and public interests while proposing methods to resolve ethical dilemmas and build consensus. It is a priority to the preventive adjustment of the legislation framework before an HBHR plan.

**Keywords:** Health Risk Management Plans. Preparedness and Control. Compliance. Health Risk Plans. Ethics for Health Plans. Risk Plan Legal Boundaries.

#### RESUMO

Este capítulo enfatiza os limites legais e os marcos éticos nacionais quando a administração pública desenvolve Planos de Risco à Saúde e Risco Biológico (HBHRP). O capítulo destaca a importância de estabelecer um arcabouço coordenado para estratégias, preparação e controle, especialmente antes da tomada de decisões e da gestão de riscos à saúde pública. A discussão concentra-se em orientações internacionais como a Global Health Security Agenda (GHSA), a World Health Organization (WHO) e a International Development Law Organization (IDLO), que propõem diretrizes para fortalecer a capacidade dos países de prevenir, detectar e responder a surtos de doenças infecciosas. As orientações internacionais voltam-se mais aos países em desenvolvimento e menos àqueles que participam dos exercícios da GHSA. O General Data Protection Regulation (GDPR) é apresentado como exemplo para explicar potenciais conflitos jurídicos. O capítulo examina

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conflitos entre intereses privados e públicos, ao mesmo tempo em que propõe métodos para resolver dilemas éticos e construir consensos. Destaca-se como prioridade o ajuste preventivo do arcabouço legislativo antes da implementação de um plano HBHR.

**Palavras-chave:** Planos de Gestão de Riscos em Saúde. Preparação e Controle. Conformidade. Planos de Risco em Saúde. Ética para Planos de Saúde. Limites Legais dos Planos de Risco.

## RESUMEN

Este capítulo enfatiza los límites legales y los marcos éticos nacionales cuando la administración pública desarrolla Planes de Riesgo para la Salud y Riesgo Biológico (HBHRP). El capítulo resalta la importancia de establecer un marco coordinado para estrategias, preparación y control, especialmente antes de la toma de decisiones y la gestión de riesgos para la salud pública. La discusión se centra en orientaciones internacionales como la Global Health Security Agenda (GHSA), la World Health Organization (WHO) y la International Development Law Organization (IDLO), que proponen directrices para fortalecer la capacidad de los países para prevenir, detectar y responder a brotes de enfermedades infecciosas. Las orientaciones internacionales se dirigen principalmente a países en desarrollo y en menor medida a aquellos que participan en los ejercicios de la GHSA. El General Data Protection Regulation (GDPR) se presenta como ejemplo para explicar posibles conflictos legales. El capítulo examina conflictos entre intereses privados y públicos, al tiempo que propone métodos para resolver dilemas éticos y construir consensos. Se prioriza el ajuste preventivo del marco legislativo antes de la implementación de un plan HBHR.

**Palabras clave:** Planes de Gestión de Riesgos en Salud. Preparación y Control. Cumplimiento Normativo. Planes de Riesgo en Salud. Ética para Planes de Salud. Límites Legales de los Planes de Riesgo.

## 1 INTRODUCTION

Effective control as epidemic risk response depends on how health and biological hazard risk (HBHR) strategies manage some variables: vaccination policies, population education, and new case monitoring. To have a responsible and continuous strategic planning process, implementation and control of all mandatory actions must be defined to reach the plan goal. In short, it is preparedness. Public administration develops responses using the existing legal framework and public and private resources.

The present work adds more author's research ( Aveni, 2023a, 2023b, 2022, 2021a, 2020a, 2020b, 2020c, 2020d, 2020e ) on planning and health risk analysis. The chapter evaluates the complexity of the ethical and legal framework and social and economic impacts before developing HBHR strategies and plans.

The chapter aims to prove the difficulty and uselessness of building and managing strategic and global HBHR without a sound legal framework. Plans are complex and have special and legal implications to be addressed before starting, and must be coordinated with the single legislation system and the Nation's moral behavior. We guess there is no global framework or principles because every Nation has ethical principles and a legal framework that could conflict with a GHSA-claimed global HBRP.

A Structured and bibliographic analysis method discusses the matter. The chapter is a discussion research. The discussion uses a dialectic or confrontation approach. We guess the rightness and the perception of the danger and the cure (the solution planned by the government) is an outcome of the ethical and legal structure of the HBHRP. Thus, the actual chapter discusses the priority of a legal framework consensus using the example of the legal framework of the privacy data protection Regulations in Europe (GDPR) and the results as a new paradigm for plans.

The chapter sections are: 1) start by defining the actual context in HBHR plan definitions focusing on health preparedness, 2) the second section discussion on data protection and the EU directive as an example of the missed link between plans and legislation framework, 3) the third section discusses the legal boundaries as a priority before planning. A concluding remarks section end the chapter.

## 2 DISCUSSION

The Global Health Security Agenda (GHSA) was launched in 2014 and is a collaborative network to enhance global health security and accelerate the implementation of the International Health Regulations (IHR) for preparedness. The GHSA 2028<sup>2</sup> goal

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<sup>2</sup> <https://globalhealthsecurityagenda.org/wp-content/uploads/2024/06/GHSA-2028-Framework-2.pdf>

framework includes the lesson learned from COVID-19 and emphasizes the need for enhanced and sustained attention for disease prevention and preparedness.

The SARS2-COVID-19 academic papers increased when the paramount health risk reached in 2020, but till today, there are no good global reports and analyses. According to the GHSA 2020 report [...] "... the GHSA has been instrumental in building and sustaining capacities to prevent, detect, and respond to numerous infectious disease threats. .... but despite significant progress, the world proved underprepared for the COVID-19 pandemic" (GHSA, 2020, 32).

The Global Health Security Agenda (GHSA) supported especially developing countries to become better prepared to respond to health emergencies through capacity building. The GHSA Legal Preparedness Action Package facilitates technical exchanges and assists countries in exploring complex issues related to WHO, IHR, amendments, and Pandemic Accord negotiations (GHSA, 2020)

Following GHSA suggestions, the strategies develop a plan, but the technical approach of the information, legal, and ethical plan boundaries are not included in that discussion. There is a missed link: the legal framework context. One problem is the priority of a legal framework before a plan when, as in Health Plans, legal boundaries impact privacy and public interest before and during the operations of the plan. Another problem is to prove the priority of a top-to-bottom approach as the only method to be used by the GHSA and other Governmental or International Organizations to comply with global response needs.

In the positivist legal approach, the public interest is the priority of a legal framework. A criticism approach is a consensus between public and private parties (Dworking, 1986, 93). The public administration and international organizations have the role of researching, coordinating, and offering solutions, but in compliance with people.

It is common sense that the executive is responsible for building the legal and ethical framework facing an emergency in time and using its prerogative of coordinative regulation. HBHR is the responsibility of the Ministry of Health of each Nation. This minister developed a plan, based on the executive strategy and depends on resources. However, building a legal boundary to prevent risks implies that public and private rights are protected and discussed before planning any.

However, even with GHSA support, when preparedness for an emergency and a short time to stop the impact of the overall legal framework, decision-makers assume to have the full right to impose restrictions because of urgency and because there is a public interest priority. Often, urgency is claimed to bypass controversial legal maneuvers or no transparent

public strategies. The executive has no right to impose or change democratic rules or human rights because of an emergency caused by unpreparedness (Aveni, 2021)

The International Development Law Organization (IDLO) suggests that a legal framework must have a consensus to handle HBHR and risk planning (IDLO, 2023). We will assume, following actual general preparedness, that the next pandemic will be used, as the last pandemic experience, a good practice, but it is not that way to have good preparedness, as was suggest by IDLO.

We must consider that, in an emergency, some conflict between the public and private spheres of action is a possibility and must be managed and discussed before the event. The most famous ones were the mandatory mass vaccination, lockdown, and the use of a green pass certificate (Aveni, 2023) that overpass human rights of mobility, free health cure of disease choice, etc.

A risk analysis usually starts by identifying the assets, ISO 31000:2018 (ISO 31000/2018) establishes that the context analysis must be performed before a risk assessment. Thus, in this context, the legal framework must be evaluated. If that or other legal boundaries are not clear or not compliant, the risk assessment and plan are compromised and should not be developed as is. A legal framework assessment and review are mandatory because of a risk evaluation.

National Public Administration Guidelines, the ones based on ISO 31000:2018, must be open to discussion with experts and corporations, health care and pharmaceutical companies, to ensure full support of the overall legal framework developed or in place. Every citizen class representative is welcome to the debate. As the process is usually a complex one, the priority is to prevent, in time, adverse events and pandemics.

## 2.1 INTERNATIONAL EPIDEMIC PREPAREDNESS AND CONTROL PRACTICE

Some HBHR preparedness and control systems were discussed and developed by WHO in 1999 (WHO, 1999). Guidelines, recently, have been developed in the US as part of a series by the Communicable Diseases Cluster (CDS) aiming for a transformative recovery process defining a preparedness day. Also, the World Bank developed plans such as the Redisse Project with the West African Health Organization (WAHO) that assigned the Mérieux Foundation and the Center for International Cooperation in Health and Development to establish 47 Epidemiological Surveillance Centers in Africa (Rameshwari et al., 2023).

Some strategies depended on the persistence of low-level transmission and intermittent outbreaks of viruses despite a claimed high coverage with immunization

schedules. Summarizing strategies for planning could be such, according to a WHO report in 1999 (WHO, 1999):

- Drastically and speedily reduce the number of susceptible individuals in those age groups where most individuals have accumulated and where the nature of contact among them facilitates virus transmission (Catch-up).

- Maintain the build-up of susceptible individuals at lower levels by immunizing a large proportion (>95%) of each new birth cohort (immunization).

- Implement additional vaccination activities.

Structure of a Preparedness Plan A risk assessment toolkit is available from the World Health Organization (WHO, 2021). The Strategic Toolkit for Assessing Risks: A Comprehensive Toolkit for all-hazards Health Emergency Risk Assessment suggests the STAR approach, which involves six key steps, uses a participatory approach and consolidation of existing evidence to describe the risks in the country (WHO, 2021):

- Identify country hazard(s) and describe the most likely scenario to require activation of the national response
- Assess the likelihood of the risk occurring
- Estimate the impact of the risk to the country
- Determine the estimated level of risk
- Draft key recommendations and priority actions based on the risk ranking
- Integrate recommendations into the national and subnational action planning process

The WHO orientation implies no limited legislation change or when facing a risk, the public interest is a priority against private and human rights. An HBHR plan, however, is not only about a virus spread risk, but ISO 31000:2018 knowledge must be included, and a context legislation analysis too.

We also know that not every nation implemented plans before the pandemic spread in 2019, and still today, not have preventive strategies to eliminate viruses and biological hazards. The lack of compliance assessment and preparedness has also been reported today.<sup>3</sup> (Aveni and Pinho, 2020). Thus, changes in legislation must be included in orientations.

A common principle to all strategies currently implemented (i.e. for COVID-19 spread) was operational. A containing spread strategy implemented was to build emergencies and a temporary legal framework. All efforts were likely to maintain the number of infected individuals in the population below the critical number required to sustain transmission of the

<sup>3</sup> <https://www.ilgiornale.it/news/interni/gimbe-accusa-conte-e-speranza-meno-morti-se-piano-pandemico-2406535.html>

viruses, and this somehow explains the lockdown strategy and the infected population above the national health capacity to react and control infected people or cure these people.

A lockdown measure is legal to narrow human rights and is an operational risk response. Thus, because it is also a constraint of public rights and human rights about freedom, the lockdown should have been directed to susceptible individuals, not to all populations. The legislation measure is a consequence of the lack of infrastructure. The hospital beds and medical doctors in each country are considerably below the number of possible transmission cases over a certain amount. That's why the increase of infection is exponential, where the cure process capacity is less than the arithmetic increase and has a limit related to investments and professionals.

So preparedness is the cause of a lockdown, and the burden of the problem cannot be reversed to all populations with human rights constraints. However, it is doubtful what possible responses are better (a legislative intervention or an increase of cure response or both) and what the alternatives are.

Without studies and analysis (preventive and operational) arises a suspicion of mass over-vaccinations or, for teenagers and children, an inexistent danger and a false health orientation from health authorities fearing consequences of bad managing choices. Thus, at what price, cost, and human life costs was the risk plan management managed? It is a fact that the inefficiency of almost all world governments caused high financial and life costs to the whole population, over the loss of workplaces, wages, and salaries. However, the government had increased profit from tax pharmaceuticals, hospitals, and medical networks. Moreover, a loss of the eldest people reduces public retirement payments. That discussion seems conveniently forgotten. That is why no complete assessment or complaint report has been published till today.

Some academics (Ayorinde, et al. 2023) reported the reemergence of the MPXV recent outbreak in May 2022 and related the reports from the Centers for Disease Control and Prevention (CDC) stating that MPX has sporadically spread to 99 countries with a total of 47 652 cases globally. On 24 October 2022 the European Health Union adopted the Regulation on Serious Cross-border Threats to Health, the Regulation on the extended mandate of the European Centre for Disease Prevention and Control (ECDC) (Delsaux, 2023). Always in Europe, the Council Regulation regarding medical countermeasures provides extra powers to the European Health Emergency Preparedness and Response Authority (HERA). Is this legislation constraint and mandatory framework changing the correct solution?

Following the academic discussion, the West African EVD epidemic and the COVID-19 pandemic have shown accurate education and science communication and how misinformation can undermine epidemic response. According to research, the success of public health interventions is communicating dependent (Olliaro and Torreele, 2022). The scholars claim that: "the one-off opportunistic partnerships of the willing are not always adequate to overcome the many challenges and gaps of an R&D ecosystem that is geared to seize market opportunities rather than addressing public health needs, especially for populations in low-resource countries" (Olliaro and Torreele, 2022).

We agree with these last authors. Only public investments and support reduce market failure harness our collective knowledge, and develop HBHR plans. However, the technological capacity to innovate and develop new medical interventions doesn't mean vaccine equity and coordinated end-to-end R&D or supply-driven pipeline that depends on public investments but relies on the private sector to deliver vaccines. There is also a willingness to assume a vaccine by the population or part of it, the decision of not assuming a substance with low or null experimentation.

The public sector sees vaccines as commodities as the necessity of the public control of the health system. Not in all countries, the Public Health system is public. Looking for production and response operation process it is necessary to build symbiotic partnerships between public and private sectors toward the shared goal of delivering appropriate health interventions as common goods. Prevention and a new focus on citizen health are necessary. A legal framework discussion is basic to encompass all public and private interests.

Based on field research (Kapiriri, et al. 2022, Kapiriri and Be LaRose, 2019) a critical point of view of current orientation on preparedness confirms that the priority of pandemic response was in setting and resource allocation activities. The four phases of the WHO emergency preparedness framework, namely Pre-epidemic preparedness, Alert phase, Control phase (Outbreak Response), and Evaluation phase (Post-epidemic), were the way to ensure priority setting during health emergencies.

However, that was not systematic, evidence-informed, and the same process for all nations. The number of infected and deaths was difficult to count because of different evaluations from nation to nation. The evaluation phase was not transparent.

## 2.2 EUROPEAN GENERAL DATA PROTECTION REGULATION (GDPR) AS EXAMPLE OF HBHR PLANNING LEGAL MISSED LINK

The regulatory legal framework could create a bottleneck when planning health hazard risk solutions and plans. It's not just a production, operational, or health system control problem. Focusing only on the outcome is flawed from the beginning. The first step must be to understand how to encourage citizens to mitigate or avoid the risk. That involves education and cooperation is not only respecting the legal rules issued to avoid risks. Every solution becomes real through widespread discussion.

In April 2016, the European Parliament and the Council issued Regulation (EU) 2016/679, which consists of 99 articles. This regulation replaced Directive 95/46/EC, composed of 34 articles issued in 1995. Privacy is a critical factor in risk management planning, particularly in situations such as the spread of the COVID-19 pandemic, when public administration and government authorities must make legal decisions and measures like lockdowns and the implementation of green health cards for travel (Aveni and Pinho, 2023).

The regulation covers risks associated with the free treatment and flow of data. It is not intended for corporations or organizations. Both public administration and private corporations have their own rules and international law framework, which are currently inconsistent. In other words, there are no privacy safeguards worldwide for individuals, governments, and corporations to have complete rights and control.

The GDPR in 2016 outlined the protection of natural persons and focused on processing personal data as a fundamental right in Europe. According to Article 8 of the Charter of Fundamental Rights of the European Union (the 'Charter') and Article 16 of the Treaty on the Functioning of the European Union (TFEU), everyone has the right to the protection of personal data concerning them. However, the right to the protection of personal data is not absolute; its function in society must be considered and balanced with fundamental rights, following the principle of proportionality.

When implementing and applying Directive 95/46/EC, it is important to consider the following basic points:

- a) Article 6 states that a process is legal even if there is no consensus.
- b) Communication is legal only when the treatment is considered in the regulation.
- c) Rights defined in the regulation.
- d) Accountability and risk analysis, with special attention given to process recording (accounting function, impact, communication, and data breach).

e) Organizational structure for privacy. This is a significant difference from previous regulations, as a risk approach is only possible with management and responsibility. According to the regulation, all private organizations must seek consensus, while Public Administration is not required to do so.

Pseudonymization for personal data ensures the safe use of data. Consent should be obtained through a "clear affirmative act establishing a freely given, specific, informed, and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement" (EU 2023, 6). Personal data should be processed with appropriate security and confidentiality measures to prevent unauthorized access or use. Member State law should comply with the legal obligation of a controller to take steps at the data subject's request before entering into the data processing.

Not all corporations have activities in European countries and could be obliged to perform identity regulation, which is very costly even with current techniques. It is difficult not only to define the concept but also to assess its feasibility. Europe claims that all corporations that use or work with European customers must comply with the European legislation (EU, 2016)

The regulations state that privacy in data manipulation, when used without consent and mainly for commercial purposes without compensation, creates a trade-off between internet services and people's free use. Private rights are controlled and protected, but the authority of the State is recognized.

The difference between the protection of rights and human rights is embedded in the Regulation. What is the connection? It is certainly not the right of a medical public or private service to conceal information that harms others or exacerbates a pandemic. However, there is no regulation concerning private and public constraints on overall health protection and prevention, but there are regulations looking for private and public organizations if found guilty of causing health damage.

Today's health security focuses on health care services rather than an overall approach to disease prevention or the right to be healthy, for example, through robust prevention of food industry manipulations (Aveni and de Assis Morais, 2021b; Mephram, 2020). A paradox occurs when a government or any organization must have and use personal data to prevent population health risks and claim consensus that personal data are not protected from the government. That raises the question of how to use personal data properly and without paradoxes. Should the parliament have the authority to decide against

freedom and the Constitution? What happens when no majority and an executive makes the decision directly? Who will be responsible afterward?

It is important to differentiate between basic research for public safety and emergencies. In our opinion, a law implementing a lockdown and using force for vaccines is not a democratic approach that is decided solely by the executive without public discussion of alternative options and a cost-risk assessment. One can easily image alternative strategies. Was it correct to use personal data to monitor individual health status or inhibit travel when open another measure or to sanitize public transport ?

The truth is that during the COVID-19 pandemic, most executives bypassed ethical and democratic decision-making, including discussions of the costs of public decisions (which were added to a conduit balance for the year). In other word the legal framework was violated and without alternative or cost analysis. Has anyone calculated the cost of human life and the public and private expenses of COVID-19, and who benefited politically and financially? What was the privacy protection control monitor? Does the pandemic spread impacts, how and what cost into privacy protection?

Looking at GDPR, imagine a loss of sensitive health data of a patient, and this data is processed first in an African and then in an Asian country. How could it be possible to trace and develop a step-by-step process of international inquiry for any of the servers involved to catch the data? And who will be responsible? What if the patient wants to send data to an Indian medical doctor he trusts more than a European? How was possible, and this a personal experience, that some people travel in a country where free to return to Italy when others, with the same vaccine protection, were not allowed?

According to the European regulation, as soon as the controller becomes aware that a personal data breach occurred, the controller should notify the personal data breach to the supervisory authority without undue delay and, where feasible, not later than 72 hours after having become aware of it. There are plenty of applications that inform about data breaches. A data breach occurs daily in small businesses and large corporations and depends on the security level of data protection. It is a tough process, and because the permission given to controllers and applications extends to these cases, the result is simply a piece of information without possible action for the people affected. It is also a forensic process, to prevent future breaches.

Independent new structures must be responsible for the flow and process of personal data. These include the Trust Supervisory Authority (or Guarantee Authority) for each country, a data privacy committee in every organization, the responsible Data Protection Officer (DPO) as a new professional figure in the EU, and the Controller of the data process

who can have a co-controller, responsible for data treatment, or who, in practice, manages data.2.3 Analysis of the Regulation utility as a tool for HBHR.

Thus, we need rules of personal data protection not only to defend the right but the solutions for every possible conflict case. It means having a best practice or a consensus on how to manage the relationship between humans, privacy, and new technologies. According to different scholars (Mephram, 2020; Spitale, Germani and Biller-Andorno, 2023; Nelson, et al. 2010) a current ethical issue subject to controversy is mainly due to the tension between individual liberty and effectiveness and could be solved by a framework or an ethic matrix. We argue that personal data protection is not the main problem in a pandemic spread, but the prevention and cure offered by the public health facilities and the self-awareness of the risks. There must be a priority scale of the legal regulation framework when HBHR plans are proposed and coordinate the whole legal framework of National and International rules..

## 2.3 CONCLUSION: HBHR ETHICAL AND LEGAL BOUNDARIES.

The coordinated link between local legislation framework before planning or assessing risk and how to activate new legislation, if embedded as possible risk response action, is and was missed in international plan orientation. Neither WHO, GHSA, nor IDLO, assumed ISO 31000: 2018 full standard by watching the context before evaluating risk, nor does GDPR dedicate orientation to be used in HBHR plans. The same happened with National legislation in front of a pandemic spread.

If DGPR public interest has priority over private identity property, the legislative priority of reducing risk is based on identity control and vaccination. Thus, probably, the next HBHR plans will continue to be issued as usual. Even if new preventive plans, today not ready, will be defined seems probable they will neglect to consider the legal framework coordination and a way to prevent legal conflicts as the priority before planning.

We guess all Nations must strengthen and mainstream priority setting or develop sound HBHR strategies. National governments should work to build a legal framework to 1) strengthen and build their healthcare systems' resilience and 2) enable effective responses to outbreaks timely. In doing so, they need to address the social determinants of health. It must avoid negative social impacts and inequitable distribution of disease outbreaks.

This approach follows a logical sequence and technique used on compliance frameworks. Many Tools exist to analyze the logical sequence following (i.e. SWOT, PEST, SMART, etc.):

- 1) to define the problem and the ethical conflict;
- 2) to define causes and legislative approaches to reduce conflicts;

- 3) a process to develop solutions for every log
- 4) to complete the process for all logs.

Building a legal framework for HBHR is mandatory. An emergency regulation and amateurism is not a good way to reduce risk impacts. Using the example of GDPR: the use of personal health information is crucial to determine if someone could potentially spread viruses. Public authorities may need to access citizens' health information without consensus. Another solution is ensuring that protection exists at the places people visit rather than the individuals themselves. In other words, citizens should be allowed to travel, and their health should be checked only once when interacting with others in public places. That presents a complex but possible risk management.

The risk could be managed following a problem-cause assessment. The spread of the pandemic and the need to reduce risks associated with mobility could depend on many causes: the public transport system is inadequate, unsterilized, and unclean. There are sick individuals with various legal and illegal motivations, and there are challenges in controlling the behavior of healthy citizens when using public transport.

Every legal problem has causes and effects that require solutions to minimize negative impacts. Some technical tools used by international organizations when defining social problems and projects are the Ishikawa model or Root Cause Analysis (RCA) (Andersen and Fagerhaug, 2006). However, it's important to note that some problems have complex causes and outcomes. The clearer the problem analysis, the easier it is to apply these techniques.

One potential way to resolve conflicts is to implement a process, or a rule for conflict resolution, which should be widely adopted by the public. For public organizations, the extension of these rules should initially involve using the OECD manual<sup>4</sup> to identify potential conflicts of interest. Here are some questions and answers:

- Question 1: What official functions or duties is Official X responsible for?
- Question 2: Does Official X have any relevant private interests?

The process to determine when individuals involved in decision-making are not in interest conflict is as follows:

1. Understand the background leading to the ethical conflict.
2. Identify the specific ethical question for clarification.
3. Consider the relevant ethical principles and national cultural values.
4. Evaluate the options for response.

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<sup>4</sup> <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0316>

## 5. Make a recommendation for a response.

Ideally, a consensus should be reached around the recommended option. However, most ethical challenges revolve around recurring issues and complex input-output processes (reference). Recurring ethical conflicts can have negative impacts on the quality of care, staff morale, efficiency, productivity, operational costs, and the organization's culture. Building a legal framework, it's crucial to ask:

- Why did the ethical conflict occur?
- What can be done to prevent the situation from recurring?

This entire process should involve all citizens but could initially be developed with representative associations (such as labor and the health system) rather than involving citizens unless it's possible to quickly vote on solutions. It is essential to consider possible solutions to the conflicts surrounding the use of personal information in health and biological hazard risk plans (HBHRP) before making any decisions or strategies.

### 3 CONCLUDING REMARKS

The chapter discussed the HBHR approach and planning with the example of a conflict that could arise when discussed involving personal data, emphasizing the need to develop strategies and operational processes to mitigate, reduce, or cover associated risks. Without a sound understanding of legal boundaries, however, existing regulations present bottlenecks or conflicts to operations. It is crucial to prioritize an overarching ethical discussion, a compliance framework regarding health information, and the use of personal and public data for any future discussions on HBHRP.

Some orientations about HBHR plans and legal frameworks are the result of the discussion: first, the plan preparedness and control should be defined after defining the ethical and legal boundaries at the beginning of the strategic process and after defining if some of the risks must be avoided with the new legal framework or emergency laws.

Second, it seems also very difficult to have a complete global HBHRP due to regional and legal differences between nations. It seems more feasible and effective to have certified experts when the public administration and private organizations developing plans.

Third: when possible, should avoid a top-down approach or constraints from the Executive as also IDLO praises. Executive dominance and infringement upon private rights must be controlled even during an emergency. The executive can't justify by unpreparedness or uncontrollable risks the damages of a weak plan. Instead, it must strive to achieve

consensus among private and public stakeholders before the risk happens using a risk analysis.

Fourth: a preventive risk approach must be put in place. The approach should address all pertinent issues while mitigating conflicts through ethical and fair discussions. The solutions developed must be fair, clearly explained, and incorporated into a compliance framework for future assessment.

Fifth: there is also a mandatory assessment for the resulting impact index publications. A collaborative approach and extensive consultations between institutions and citizens should be fostered to proactively shape HBHRP strategies. Building a risk management culture and making decisions based on the right rationale, which includes promoting health education and avoiding politically and emotionally driven or amateur decisions, are essential to reduce risks.

Transparency of a risk plan is mandatory. All health risk communications, especially those with societal impacts such as mental and infectious diseases, should respect rights and be free from any threats, including those emanating from public administration. Future emergencies must strive to avoid the mistakes of the past crisis, steer clear of tragic comedy and negative publicity, and eliminate bad actors and political corruption by addressing a better coordinated legal boundary.

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