PUBLIC HEALTH – METHODOLOGY, ENVIRONMENTAL AND SYSTEMS ISSUES

Edited by **Jay Maddock**

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Preface

Public health can be thought of as a series of complex systems. Many things that individual living in high income countries take for granted like the control of infectious disease, clean, potable water, low infant mortality rates require a high functioning systems comprised of numerous actors, locations and interactions to work. Many people only notice public health when that system fails. With widespread globalization occurring, public health issues have become transnational. Infectious diseases like SARS, H1N1 or the common cold can be transmitted within hours across national borders via airplane. Pollution and environmental degradation can be outsourced from high income countries to lower income countries via trade imbalances in manufacturing or recycling. Even NCDs can be transmitted via the global market for tobacco and fast food. For public health to continue to protect the public from these threats clear systems thinking with the development of novel methodologies is needed.

The first section of this book explores novel measurement and methodologies for a variety of public health concerns. Chapters include assessing risk and uncertainty, measurement of mental health in children, the use of the Ames assay and measuring gene by environment interactions. The second section examines issues in the food system and environmental risks. A safe, reliable food system is essential for public health in every country. Issues in this section include the presence of chemical residues in animal food products, bacteria in food and iron deficiency anemia. The two environmental health chapters include snakebites, one of the oldest public health problems and waste minimization in nanosilver productions one of the newest public health concerns. The third section of the book reviews some of the major challenges in health systems. These include health resources, technology and management of medical devices. The role of private business in public health is also explored. The final section contains a variety of issues related to global health. This includes the rise of NCDs in low and middle income countries, neglected diseases related to poverty and health and longevity medicine. A chapter of alcoholism and mortality examines the effects of a public health system breakdown. Final chapters review men's health, insomnia and a gendered analysis.

This book exemplifies the global nature of public health. All six inhabited continents are represented by authors in this book. The home country of the authors include

Australia, Turkey, Poland, Mexico, Brazil, Canada, Korea, The Netherlands, Japan, Benin, Malaysia, USA, Russia, Romania, Taiwan, Iran, Costa Rica, Columbia, Sweden, Germany and Italy. This trans-national list of authors provides an important view of the future of public health and the increased need to collaborate with public health professionals across the world to address the myriad of public health issues. I hope you enjoy reading the following chapters. I find them to be insightful and to provide an excellent collection of the ways that methodology advances and systems sciences are being used to protect and promote the public's health. Aloha.

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Section 1

Measurement and Methodology

1

Potential Risk: A New Approach

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1. Introduction

Risk is a polysemic term that has been transformed throughout the historical process, but has always been associated to the idea of predicting an unwanted future event.

The first rudimentary notion of what can be called risk, may have arisen, according to Covello and Munpower (1985), around 3200 BC in the valley between the Tigris and Euphrates Rivers, where lived a group called "*Asipu*". A major function of this group was to help people who needed to make difficult decisions. The "*Asipus*", when sought, identified the scale of the problem, the alternatives and the consequences of each alternative. Then, they drew up a table, marking the positive and negative points of each alternative to indicate the best decision.

With the great voyages in the fifteenth century it became necessary to evaluate the damage caused by the potential loss of ships. Emerges then the term risk, with connotations similar to what is meant today, but the understanding of its causes was related to accidents and, therefore, impossible to predict. The development of classical probability theory, in the mid-seventeenth century, to solve problems related to gambling, allowed the start of the process of quantifying the risks, but the causes were still credited to chance.

Only from the nineteenth century, associated with the dominant thinking of the primacy of science and technique and propelled, among other factors, by the discoveries of Pasteur, emerged the association of risk with prevention, i.e., if the causes are known and quantified one can predict the undesirable effects.

The advent of modernity has produced and incorporated to the human way of life a variety of technologies and the risk became the distinguishing feature of this generated complexity. More and more, the sources of hazards[1] were associated with daily social practices. In today's society, it is difficult to separate the manmade dangers of the "natural" dangers (Beck, 2003). A flood for example, that occurred as a completely spontaneous phenomenon, today can happen as a consequence of human action on nature. This new concept that the term risk assumes defies the human prediction capacity and rationality, because its causes are no longer accidental and the causes are not always known, or they are possible effects of the technologies generated by man himself.

[1] Hazards are "physical, chemical or biological agents or a set of conditions that present a source of risk." (Kolluru, 1996. p. 3-41).

2. Risk and probability

The first report of a quantitative risk evaluation applied to health goes back to Laplace, in the late eighteenth century, which calculated the probability of death among people with and without vaccination for smallpox. With Pasteur's studies in the late nineteenth century, it was possible to use the tools of statistics to evaluate the factors related to communicable diseases, giving birth to the concept of epidemiological risk (Covello; Munpower, 1985, Czeresnia, 2004).

Epidemiological studies about contagious diseases have two very specific characteristics. The first refers to the object, which is only a source of damage. The second relates to the goals, which aim to determine the relationship between cause and effect, i.e., between exposure and disease. So, even with multifactorial determinants, it's an unidimensional evaluation. Therefore, in a evaluation between exposed and unexposed, the concept of risk approaches the definition of probability. However, when the objective includes the judgment about the severity of the injury or the comparison of different injuries in different exposures, the probability becomes one of the information that compose the concept of risk.

Therefore, the development of probability enabled the start of the process of quantifying risk. However, it's noteworthy that probability and risk are different concepts to most subjects. While the probability it's mathematically defined as the possibility or chance of a particular event occurs, and is represented by a number between 0 and 1 (Gelman; Nolan, 2004, Triola, 2005), the risk is associated with the probability of occurrence of an undesired event and its severity and cannot be represented by only one number.

If two events A and B have, respectively, 0.10 and 0.90 probability of occurring, the event B is classified as nine times more likely to occur than the event A. However, one can not say that the event B has a greater risk that the event A. For the concept of risk, is fundamental to know how much the event will be harmful. The evaluation of the probabilities of occurrence of the events A and B is done purely with mathematical analysis, while the risk assessment requires judgment of values. Thus, all observers will agree that the event B is more likely to happen than the event A, but not all should agree on which event represents a greater risk, knowing, or not, the damage.

As already explained, the notion of risk has been transformed throughout human history, it being understood nowadays as a theoretical elaboration that is historically constructed in order to mediate the relationship between man and the hazards, in order to minimize losses and maximize the benefits. Thus, it is not a greatness that is in nature to be measured, is not independent of the observer and his interests. It is formulated and evaluated within a political-economical-social context, having a multidimensional and multifactorial character (Fischhoff et al., 1983, Covello; Munpower, 1985, Beck, 2003, Hampel, 2006)

3. The risk in the modern era

The beginning of the twentieth century was marked by great scientific advances. The application of this knowledge produced new technologies such as X-rays, nuclear energy, asbestos and formaldehydes. The rapid use of these technologies as if they were only sources of benefits brought consequences to public health and to the environment, which only came to be perceived and understood by society, from the 70s of the last century. The disclosure of these risks led to pressures on governments, to control occupational,

environmental, chemical agents and radioactive agents risks. In this context of large social movements, the need for State intervention was strengthened, in order to regulate the use of products potentially harmful to health and the environment (National Research Council, 1983, Lippmann; Cohen; Schlesinger, 2003, Omenn; Faustman, 2005)

The regulation of health risks is understood as a government interference in the market or in social processes, in order to control potentially damaging consequences to health (Hood; Rothstein; Baldwin, 2004). The model of the regulatory system, deployed in each country depends on political, economic and social conjunctures. Therefore, in the 1970s, while European countries exerted, initially, its regulatory power, by means of direct administration bodies of the State, the United States exercised this power, mainly, through independent and specialized agencies.

Currently, most European Union countries use the model of regulatory agencies (Lucchese, 2001). In Brazil, this role it's exercised in a hybrid way, because the National System of Sanitary Surveillance (*Sistema Nacional de Vigilância Sanitária* - SNVS) is composed of a regulatory agency in the federal sphere, the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA), but in most states and municipalities the regulation is exerted by direct administration.

The new technologies permeate the entire society and, therefore, influence and change the established social relations. These technologies are characterized by having intrinsic risks, by the possibility of adding new risks throughout their life cycle and by the incomplete scientific knowledge about the types of risks they generate and their interactions in different situations. Thus, the regulatory process occurs, in most cases, in situations of epistemic uncertainty, where risk factors are presented in a diffuse way, requiring from sanitary surveillance the use of mutually complementary strategies of health protection.

As for the economic and social consequences related to the decisions of regulatory actions were amplified by the globalization process, as many decisions go beyond national borders and bring into play great interests. The first regulatory decisions showed that the process of definition and regulation of risk is an exercise of power, full of interests and political, economical, and social concepts, and can strongly influence the allocation of public and private resources of a nation (Slovic, 2000, Fischhoff; Bostrum e Quadrel, 2005).

Thus, the risk conceived as the probability of occurrence of an undesired event, calculated by specialists and presented to society as an absolute and neutral truth, began to be questioned. The conflicts of interest over the division of risk showed that it is not possible to separate the technical analysis about the risks from the decisions of who should be protected, from the costs and from the available alternatives, because the studies or risk evaluations occur, necessarily, to subsidize decision-making.

4. Other dimensions of risk

The fact that the calculation of risks undertaken by experts no longer represented the absolute truth and, also, the impossibility to eliminate the risks produced by the new technologies, because the benefits would also be suppressed, bring up new angles for the analysis of the phenomenon. Therefore, come into play other dimensions of risk as acceptability, perception and confidence in the regulatory system.

In beginning of the 1980, the U.S. Congress, realizing the need to structure a model of risk assessment that had wide acceptance, as well as standardizing the realization of studies in various areas, established a directive that designated the Food and Drug Administration (FDA) as responsible in coordinating a study for the harmonization. The FDA commissioned the National Academy of Sciences of the United States, which developed the project, whose results were of notorious and acknowledged importance, structuring the foundation for the paradigm of risk regulation (National Research Council, 1983, Omenn, Faustman, 2005).

This study, published in 1983 under the title *Risk assessment in the government: managing the process*, known internationally as the *Red Book*, establishes a process with seven stages: (1) Hazard identification, (2) dose x response assessment, (3) exposure assessment, (4) risk characterization; (5) Establishment of regulatory options, (6) Decision and implementation of the option of regulation, (7) Evaluation of the regulation. All steps occur with the participation of various actors, experts or not. The stages (1 to 4) are classified as risk assessment and are of technical and scientifically base. The other stages (5 to 7) are part of risk management, which, taking into account the information obtained in the first stage, evaluate and implement the best regulatory options, considering economical, political and social issues.

A diagram of the paradigm of risks applied to the area of health surveillance is represented in Figure 1.

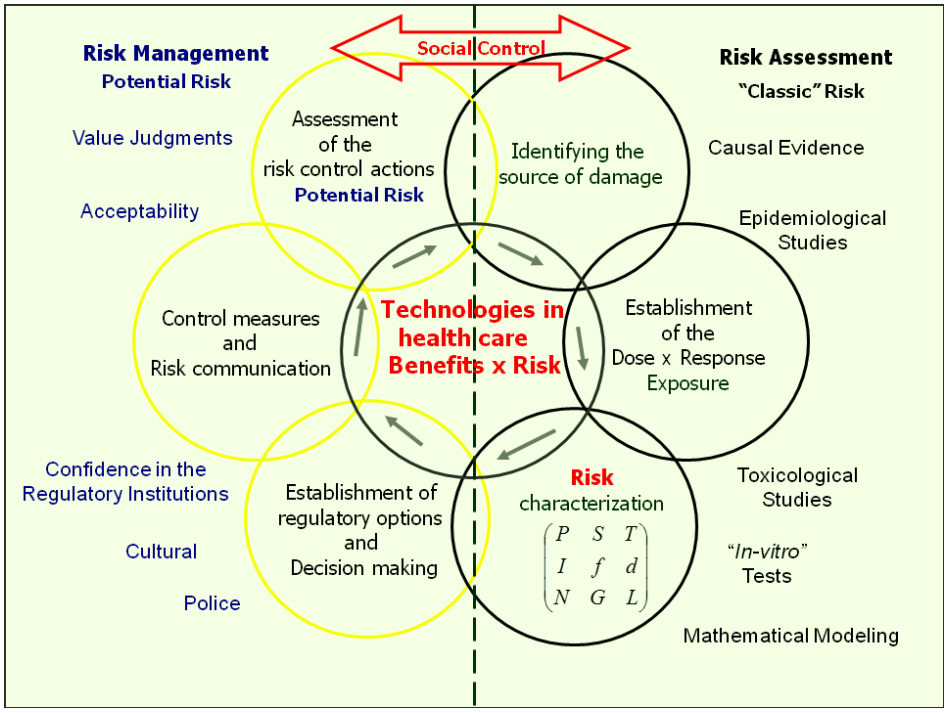

Fig. 1. Diagram of the paradigm of risks applied to the area of health surveillance. Adapted Omenn and Faustman (2005, p. 1084)

In the center of the map is the information that characterizes the particularization of the model for the health surveillance: the object of study. Objects of action of health surveillance, herein referred to as technologies in health care, have three basic characteristics: they are of interest to health, produce benefits and have intrinsic risks. It is these characteristics that justify the action of health surveillance about the technologies for health.

In this triad, the risk is a feature that mobilizes a wide set of control strategies. As the risk is intrinsic to the object, it cannot be eliminated without eliminating the object, it can only be minimized. All technologies for health present some kind of risk and, if there is any that does not possess risks, it probably will not be object of action of the sanitary surveillance.

For possessing risks inherent in their nature, the technologies should be used in the observance of the bioethical principle of the benefit (Costa, 2003, 2004)

The diagram of the paradigm of risk, represented in Figure 1, is divided in half, pierced by social control and the object of study. The right side represents the field of risk assessment and the left side, the field of risk management. Risk assessment is the use of objective evidences to define the effects on health due to exposure of individuals or populations to hazardous materials or situations. Risk management refers to the process of integrating the results of risk assessment with social, economical and political issues, weighing the alternatives and selecting the most appropriate to the regulatory action (National Research Council, 1983).

Risk assessment consists of three steps: identifying the source of damage, establishment of the dose x response and risk characterization. Risk identification is basically the answer to the question: which component of this health technology causes an adverse event? It is a question that can be answered based on causal, toxicological, and epidemiological evidence or in vitro tests (National Research Council, 1983, Omenn; Faustman, 2005).

In the second stage, two questions must be answered: how exposures occur? How is the relationship between exposure x effects (dose x response)? At this point, should be evaluated the conditions (intensity, frequency, duration, susceptibility and exposure period), in which the individuals or the populations are exposed. The second question should be answered with epidemiological, toxicological, experimental, and in vitro studies, using extrapolations or mathematical modeling, to establish the probability of occurrence (National Research Council, 1983, Omenn; Faustman, 2005).

The last step is the characterization of the risk, in the classic sense. It is a moment of synthesis, when setting the damage likely to occur and its probability (P) the severity of the damage (D), the lifetime lost (T) and the vulnerabilities of exposure, as the intensity of exposure (I), the frequency of exposure (F), the duration of exposure (D), the exposed population (N), the populational groups (G) and the accessibility to the geographical location of the population (L).

The risk assessment is a moment eminently technical and scientific, in which the theoretical models, the experimental procedures and the validation of the results are the elements of the performed studies (epidemiological, toxicological, in vitro and mathematical modeling, among others), so they can have rigor and scientific legitimacy. However, the evaluation models are not independent of the observers and their objectives (Czeresnia, 2004).

Risk assessment is not always possible to be performed quantitatively. In the case of the ionizing radiations, for example, the studied populations (Hiroshima and Nagasaki, Chernobyl and radiotherapy patients) were exposed to high doses, with high dose rates. Thus, it was necessary the use of the precautionary principle to postulate that, by extrapolation of the results of exposure at high doses, one must consider the linear relationship dose x response, without a threshold of exposure. Similar situations also occur in exposures to other physical and chemical elements, reflecting the complexity of the processes of risk assessment.

Based on information from the risk assessment, begins the process of management, conducted by the regulatory authority, also composed of three steps: establishment of regulatory options and decision making; implementation of control measures and risk communication and; assessment of the control actions.

In the first stage, are raised the possible actions that can minimize the risks, when the political-economical-cultural viability of each of the actions should be evaluated. Generally, there are several possibilities of regulation, when the best should be chosen. The best option is not, necessarily, the one with lowest risk or the one you want, it's the possible option in the evaluated context. The result of the value judgments will be the establishment of the limits of acceptability and of the control activities needed to keep the risks within these limits (National Research Council, 1983, Omenn; Faustman, 2005). In the case of the sanitary surveillance, this is the moment of development and publication of the standards for sanitary regulation.

The next step is the moment to inform society about the risks being regulated and the control measures being implemented. Parallel to the communication process, the regulatory authority should take the necessary measures, so that the control measures are effectively fulfilled by the regulated segment. An autonomous regulatory authority, with financial resources and skilled technicians, is a sine qua non condition for the implementation of the regulatory actions. However, the tradition of the institutions, of the regulated segment and of the society is essential so that risk control actions cease to be just rules and start to be practiced (National Research Council, 1983, Omenn; Faustman, 2005).

The last step is the evaluation of the entire process. It's the end of the first cycle and, perhaps, demands the beginning of a new cycle of risk assessment and management. To carry out the assessment, understood as a trial on a social practice or any of its components, in order to assist in decision-making, it is necessary to formulate strategies, select approaches, criteria, indicators and standards (Vieira Da Silva, 2005).

5. The potential risk

As seen so far, risk is a theoretical construct, historically grounded and, by the characteristics with which it presents itself in modern times, requires a regulatory system focused on protecting the health, due to the attributes that present the new technologies.

In the presented model of regulation of risks, the risk, in the classical sense, no longer has the central role, when passing from evaluation to management. In the process of risk management, the actions of health surveillance are focused, in general, on the control of risks and on the source of risks. In risk evaluation, the hazard is identified, related to the