Chapter 2
Risk Assessment, Impact Assessment, and Evaluation

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Introduction

Public health evolution has experienced some relevant hits throughout history. One was the improvement of sanitary conditions and the control of infectious diseases. The second focused on the contribution of individual behaviors to non-communicable diseases and premature death. The most recent one conceptualizes health as a key dimension of quality of life (Kickbusch 2003).

The World Health Organization (WHO) has shown in subsequent reports that global health can extensively be improved both by a systematic identification and assessment of more relevant underlying causes of diseases and injury, and by taking actions for preventing or reducing those risk factors. Behavioral risks including alcohol, tobacco and drugs consumption, unsafe sex or eating habits (leading in some countries to high rates of overweight, obesity and high levels of blood pressure and cholesterol), together with environmental factors such as poor water sanitation or indoor and ambient air pollution have proved to be responsible for about one-third of the total global burden of disease throughout the world. Tackling causal risk factors effectively offers the prospect of millions of premature deaths being prevented, and a great improvement on quality of life for populations in all countries (WHO 2002, 2004, 2009). Health services, although very relevant in defining the course of the illness process, are less important in determining population's health (Kemm 2001; WHO 2004, 2009). In this way health protection and health promotion, averting and diminishing major risk factors, have been set up as core priorities worldwide for the last decades.

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An early model developed to get a better understanding of what contribute to sickness and health was the one proposed by Lalonde (Lalonde 1974), which grouped risk factors into four levels: human biology, lifestyles, environment and health organization. Under this framework it was considered that the greatest efforts to improve population's health status should be done in the field of individual behavior changes, using a narrow approach of epidemiological association between individual risk factors and health outcomes.

However, it is now widely accepted that the causal pathway leading to an adverse health outcome does not depend on isolate risk factors but on the intricate relation of those elements with broader socioeconomic, cultural, environmental, and political conditions (WHO 2002; Dahlgren and Whitehead 2007; Kemm 2007; Metcalfe and Higgins 2009). This approach was already acknowledged in the preamble of the constitution of WHO when referring to the concept of "health" (WHO 1948), and in the Ottawa Charter (WHO 1986). The so-called social view of health generated under this new framework focused its attention not on individual behaviors and communities at risk but in the whole population within a setting. Public health targets moved towards building healthy communities, healthy workplaces, strengthening the wide range of social networks for health, and increasing people's capacity to lead healthy lives (Kickbusch 2003).

From late 1980s, this approach was widening by considering not only the models and determinants explaining the health status of the population, but also how certain factors (unemployment, unsafe workplaces, housing deprivation, etc.) contribute to health disparities within a population both at group and individual level (Wilkinson and Marmot 2003; Sen 2004; Gehlert et al. 2008; Harris-Roxas and Harris 2011). Analyzing social, environmental, and working conditions as upstream factors in multilevel models can improve the design and implementation of interventions targeted at levels downstream from those conditions (Gehlert et al. 2008). WHO has placed significant emphasis on this perspective by establishing the Commission on Social Determinants of Health (Solar and Irwin 2010).

The design and implementation of healthy public policies that, directly or indirectly, address health determinants was proposed by the Ottawa Charter (WHO 1986) as a valuable promoting action to achieve a substantial improvement in quality of life, conceptualizing health as a "resource for living" (Kickbusch 2003). In this way, the Charter urged health to be included on the agenda of policy makers in all sectors that might affect the every-day life of people at all levels. Healthy public policies has been defined as a policy that takes accountability of all possible health impacts, acknowledging the causal pathways resulting from the modification of upstream health determinants (mostly environmental conditions, living and working conditions, and community influences), and related risk factors downstream (WHO 1986; Kemm 2001; Joffe and Mindell 2004; Metcalfe and Higgins 2009; Kearns and Pursell 2011). This approach was strengthened by subsequent revisions and strategies such as *Health for All in the Twenty-first century* (WHO 1999) which underlined that the majority of health determinants reside outside the health sector, and highlighted the need for a complex intersectoral political and social collaboration.

To this respect, the European Union, first at the Treaty of Maastricht and more explicitly at the Amsterdam Treaty, declared that "a high level of health protection shall be ensured at the definition and implementation of all Community policies activities" (European Communities 1997). The strategy of "Health in All Policies" (HiAP), adopted at the Finnish European Union (EU) Council Presidency in 2006 (Ståhl et al. 2006), has become increasingly important in Europe as governments realize that reducing inequalities and improving health are fundamental enablers for economic development (Solar and Irwin 2010; Lin et al. 2012). The second programme of Community action in the field of health (2008–2013) of the European Parliament and Council also calls "to support the mainstreaming of health objectives in all Community policies and activities" (European Commission 2007).

The increasing call for a better protection of citizen's health demands a better understanding of the existing forms for characterizing health impacts of policies, and the purposes for which they are undertaken. Differences in concepts, frameworks and procedures among various approaches (risk assessment, health impacts assessment, etc.) have arisen in relation to specific issue of concern (i.e., waste disposal; electromagnetic fields, biotechnology, social disparities, urban planning, etc.), or due to perceived weakness in practice (i.e., the food safety crisis that took place in late 1980s and 1990s as the occurrence of BSE (mad-cow)). The present chapter intends to provide an overview of some of those approaches, especially risk assessment for health and health impact assessment, considering them in the political context they appeared, and the purpose they have been applied for. Finally some attention will be paid to the process called "policy evaluation," as a different tool used in the improvement of healthy policy formulation and practice.

Risk Assessment

Every aspect of life involves risk, and how we deal with it depends largely on our understanding of the concept and its assessment. Although there are many possible definitions about "risk," from a public health perspective it is broadly conceived as "the probability of an adverse health outcome, or a factor that raises this probability" (WHO 2002, pp. 9). The introduction of this concept establishes quite an advantageous step forward by contrast with the idea of "hazard," which refers to any agent (biological, chemical or physical) or situation having the potential to cause harmful effects when a person or population is exposed to that agent or situation (IPCS 2004; FAO/WHO 2006). In this way, hazard refers only to a qualitative perspective related to the inherent characteristics of the agent (i.e., intrinsic toxicity of a chemical, or pathogenicity and virulence of a microorganism). However, the use of risk implies the possibility to quantify how probable is that a person or a population might get in contact with an hazardous agent or a risk factor (this means to become exposed to), and at the same time allows to quantify the severity of the possible consequences of that exposure, mainly in terms of health outcomes but also as socioeconomic impact.

So, in summary risk assessment methods consist of models that describe and predict how potential sequences of events, resulting from human actions or natural failures, can lead to exposure, while accounting for the magnitude and severity of the consequences (Ricci 2006).

This terminology and approach has been widely used in the fields of chemical or food safety when, as an example, we refers to the human exposure to toxic substances present in the environment or in foodstuff. It can however also be applied to other hazardous situations or risk factors related to behavioral options or to the socioeconomic environment where people live (WHO 2002, 2009). In this way, and assuming the framework of the social determinants of health mentioned before, the causal pathway leading to a particular health outcome can be displayed as complex diagrams where public interventions (policies and programs) are key upstream health determinants, which implementation would generate different exposure scenarios by modifying downstream the distribution of certain risk factors in the population (Joffe and Mindell 2002, 2006; Dahlgren and Whitehead 2007; Solar and Irwin 2010). In the *World Health report 2002* by WHO focused on "Reducing Risk, Promoting Healthy life," a different terminology is used, referring to upstream health determinants as distal risk factors, and downstream health determinants as proximal risk factors (WHO 2002). Whatsoever, it is essential to consider the whole causal chain when addressing the potential impacts of a policy on health. This broader analysis of the potential impacts of a policy on the population health is the main objective of the present book, being discussed in several chapters.

Early Framework and Procedure for Risk Assessment

The different aspects of the physical environment that can influence human health have been the focus of many studies in the last decades, and build the roots of the risk assessment approach. A wide range of human and natural activities from protecting air and water to ensuring the safety of food, drugs, and consumer products such as toys, have made of risk assessment an important public-policy tool for informing regulatory and technologic decisions, setting priorities among research needs, and developing approaches for considering the costs and benefits of regulatory policies. Today, national and international legislation dealing with environmental and health protection require from risk assessment to rank and guide the selection of optimal management choices (Ricci 2006; NRC 2009).

The National Environmental Policy Act (NEPA 1969), adopted in 1969 set up the foundation for the environmental policy in the United States (USA), including as a major objective the protection of human health and welfare. This far-reaching legislation is a reference in the early development of the risk assessment procedure as a tool to understand and address a wide variety of hazards and situations that pose chronic health risks. This process was instrumental for the U.S. Environmental Protection Agency (EPA) and other federal and state agencies, industry, the academic community and others for several years, although, it is not till 1983 that a

harmonized definition and uniform guideline was proposed by the U.S. National Research Council (NRC) in the *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983). In this document also known as the Red Book, risk assessment was defined as "the characterization of the potential adverse health effects of human exposures to environmental hazards," including both, quantitative and qualitative expressions of risk. Excluded from this concept were the analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and the analysis of the economic and social implications of regulatory decisions (functions assigned to risk management) (NRC 1983, pp. 18).

In this initial model, risk assessment procedure was divided into four major steps:

(a) *Hazard identification* involving the identification of all situations or agents capable of causing adverse health effects in a particular exposure scenario, characterizing the nature and strength of causation based on data from epidemiological studies, animal-bioassays, in vitro effects studies, and comparison of molecular structures. Key information to be considered under this stage refers also to toxicokinetics (how the body absorbs, distributes, metabolizes, and eliminates chemicals) and toxicodynamics (effects that chemicals have on the body) as well as potential mode of actions (or toxicity pathways) related to the health effects identified (NRC 1983; EPA 2012).

(b) *Dose–response assessment* describing the relationship between the amount and condition of exposure to an agent (the dose provided), and the probability and severity of an adverse health effect (the responses) in the exposed population. The response assessed may be the incidence of some endpoint or health outcome (i.e., cancer incidence, incidence of a critical effect, etc.), or it may describe the magnitude of response (i.e., magnitude of IQ loss). Traditionally different mechanisms were proposed for carcinogenic (non-threshold) and other health effects (threshold), although this is currently under revision (NRC 2009). The information is obtained by reviewing the scientific evidence generated in epidemiological and toxicological studies, which implies the use of extrapolating methods and assumptions (i.e., from high to low dose or from animal bioassay to humans). Those statements introduce quite an important source of biological uncertainty that need to be properly described and justified (NRC 1983; EPA 2012).

(c) *Exposure assessment*, as a process of measuring the intensity, frequency, and duration of human exposures to an agent currently present in the environment, or hypothetically released as result of future human actions. The information gathered at this stage refers normally to the distribution and concentration of a hazard in the environment allowing the characterization of the exposure pathways (contaminant source or release, environmental fate and transport, exposure point or area, exposure route, and potentially exposed population), as well as data on behavioral and physiological characteristics of the actually or potentially exposed population (NRC 1983). Modeling is often used to estimate the environmental concentration of hazards that people are exposed to in relation to a source of emission (NRC 1994). Biomonitoring (measuring concentrations of

the chemicals, their metabolites, or their adducts in human specimens) is another approach used for exposure assessment (Calafat et al. 2006).

(d) *Risk characterization* is the final step where the exposure and dose–response assessments are combined in estimating the nature and the magnitude of human risk according to the different exposure scenarios identified. As a fundamental step in supporting decision making, all key findings and important considerations about risk need to be clearly reported at this stage, including factors such as the nature and weight of evidence for each step of the process, the estimated uncertainty of the component parts, the distribution of risk across various sectors of the population, and the assumptions contained within the estimates (NRC 1983, 1994; EPA 1984, 2000, 2012).

The risk assessment process was proposed to be objective, transparent, systematic, science-based, well-planned, fully documented, subjected to peer review, and updated as new evidence become available (NRC 1983). Those attributes and values are currently shared by any field and context where risk assessment is being applied (IPCS 2004; FAO/OMS 2006; NRC 2009; EPA 2012).

Each step of the risk assessment process is subject to scientific judgments and policy options such as how to deal with uncertainty, type of inferences and assumptions applied when data availability is inconsistent (also known as defaults), or those choices affecting the utility of the assessment's results for decision making. The expression "risk assessment policy" is used to refer to all those considerations which should be explicitly distinguished from the political, economic, and technical concerns inherent to the design and choice of regulatory strategies (risk management) (NRC 1983, 2009; FAO/WHO 2006). Default values should be scientifically justified, and be based on existing data and representative of the missing parameter. The different agencies and international organizations involved in risk assessment have established and published a set of defaults values used in their evaluations (i.e., EFSA 2012; EPA 2011a, b). Documentation of all assumptions contributes to the consistency and transparency of risk assessment.

Under this framework, risk assessment was proposed to be undertaken independently from risk management to ensure the impartiality of the outcomes, although a fluid communication and interaction in both directions was strongly encouraged (NRC 1983). However, this independency has been taken sometimes to the extreme of making of the risk assessment a tool with no clear purpose within the policy-decision process, generating a gap between science and policy action (Montage 2004).

Some Application of Risk Assessment in the Formulation of Policies and Strategies

A wide variety of guidelines and methodological guidance have been produced worldwide on the bases of this procedure, especially to support the regulation of chemical substances and to assess the health risk of human exposure to environmental

hazards. It is worth mentioning the extensive work done by EPA applying risk assessment to inform a broad range of regulatory decisions such as: restriction of pesticide usage, setting remediation goals to hazardous waste site, usage of hazardous materials, establishing standards for ambient air quality, or standards to control the emissions of hazardous air pollutants. EPA's 2012 report, *Framework for Human health Risk Assessment to Inform Decision Making*, provides a detailed list of guidance and manuals that EPA has developed for different topics, and for the performance of each one of the four steps of the risk assessment process. A comprehensive set of links to key EPA tools and guidelines can also be accessed at EPA's Risk Assessment Portal (http://www.epa.gov/risk/). The general output of the process applied by EPA, especially as part of site remedial investigations, refers to numeric estimate of theoretical risk, focusing on current and potential future exposures and considering all contaminated media regardless if exposures are occurring or are likely to occur. By design, it generally uses standard (default) protective exposure assumptions when evaluating site risk (EPA 2000, 2011b, 2012).

The ATSDR (U.S. Agency for Toxic Substances and Disease Registry) also developed a procedure called *Public Health Assessment* (PHA) that incorporates the same four steps of the risk assessment process, but differing from EPA approach by focusing more closely on site-specific exposure conditions regarding past, present or future polluting activities affecting particular communities. In addition to environmental and exposure data, PHA also incorporates specific community health concerns, and any available health effects data (toxicological, epidemiological, medical, and health outcome data) to provide a site-specific evaluation, and identify appropriate public health actions (ATSDR 2005).

The International Programme on Chemical Safety (IPCS) set up by WHO intends to provide governments as well as international and national organizations with consistent procedures and tools to ensure the safety of human health and the environment regarding all activities involving chemicals. It covers a full range of exposure situations from the natural presence of chemicals in the environment to their extraction or synthesis, industrial production, transport, use, and disposal. So it comprises aspects related to environmental health, occupational health or food safety, among others.

In last decades, IPCS has produced harmonized risk assessment methods, as well as risk assessments reports on specific chemicals based on the Red Book's four steps-procedure. These products include Concise International Chemical Risk Assessment Documents, International Chemical Safety Cards, Pesticide Data Sheets, Poisons Information Monograph, Standards for drinking water quality, or Monographs and evaluations of contaminants and additives in foodstuff. IPCS also plays a very important role in the implementation of international agreements such as the *Globally Harmonized System of Classification and Labelling of Chemicals* or the *Global Environment Monitoring System—Food Contamination Monitoring and Assessment Programme (GEMS/Food)*. An exhaustive list of publications, tools and links referring to IPCS activities can be obtained from the IPCS Web site (http://www.who.int/ipcs/en/).

Risk assessment has also been an important element in improving the formulation of policies in the domain of food safety. The increasing complexity of the food chain,

the rapid globalization with greater movement of people and goods, the drastic changes in dietary patterns and food preparation preferences, the emergence of new pathogens, or the introduction of new technology in food processing and manufacturing operations are just some of the challenges that modern food safety systems must confront. The food safety crises in the 1990s, particularly the one related to the bovine spongiform encephalitis, generated a significant controversy regarding existing monitoring and control measurements, and highlighted the need to assume a more systematic, scientific and interactive approach to respond to food safety problems. To this respect, and in order to meet the new demands of modern food safety, FAO and WHO proposed from 1995 that governmental bodies would adopt a new structured decision-making process called "*Risk analysis*." Under this framework the formulation of new food safety policies should be done following an iterative, ongoing and highly interactive process involving a systematic and transparent collection, analysis, and evaluation of all relevant scientific and nonscientific information about food hazards, so the best option to manage the associated risks could be selected (FAO/WHO 1995, 2003). Risk analysis can be used for example to characterize the level of risk associated to the presence of a certain chemical in a foodstuff helping governments to decide which, if any, actions should be taken in response (i.e., setting or revising a maximum limit for that contaminant, review of labeling requirements, etc.). This process also enables authorities to identify the various points of control along the food chain at which measures could be applied, to weigh up the costs and benefits of different options, and to determine the most effective one(s) (FAO/WHO 2006). In Europe, this framework was adopted in 2002 by the General Food Law Regulation (Article 6 of Regulation 178/2002) as the basis for the future development of all EU food safety legislation.

Risk analysis includes three independent but closely interrelated components: risk management, risk assessment and risk communication (FAO/WHO 2003, 2006). As stated in the Red Book, risk analysis framework also emphasis the need for a quite distinctive separation between risk assessment and risk management though keeping a frequent and continuous dialogue between the two components. At international level, risk management defining food safety standards is undertaken by different Codex Committees (Committees on Food Hygiene, Meat Hygiene, Food Additives, Contaminants, Pesticide Residues, and Residues of Veterinary Drugs in Foods), while risk assessment providing the science-based support for those standards is assumed by the three Joint FAO/WHO Expert Bodies: the Joint Expert Committee on Food Additives (JECFA); the Joint Meeting on Pesticide Residues (JMPR); and the Joint Expert Meeting on Microbiological Risk Assessment (JEMRA). Additional risk assessments may be provided, on occasion, by ad hoc expert consultations, and by member governments that have conducted their own assessments (FAO/WHO 2006). In Europe, the European Commission, European Parliament and EU Member States are the key risk managers in the EU system. They are responsible for making European policies and taking decisions to manage risks. The European Food Safety Authority (EFSA), based in Parma (Italy), is the responsible for food related risk assessment in the EU, producing scientific opinions and advice to support the Commission and other risk managers in the policy-making processes. Other EU agencies who apply risk

assessment are: European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), and the European Environment Agency (EEA). In addition three non-food Scientific Committees managed by DG SANCO (SCCS, SCHER, SCENIHR) and the Scientific Committee on Occupational Exposure Limits (SCOEL), managed by DG Employment complete the EU risk assessment system.

The process to conduct risk assessment within the risk analysis framework consists of the same four steps proposed in the Red Book's procedure, with the exception that the "dose–response assessment" step is here designated as "hazard characterization" (FAO/WHO 2003, 2006), but keeping a similar approach. An additional phase to the procedure in this field is the so-called "*risk profile*," a frame that contextualizes the food safety problem, defines public health objectives, and identifies priorities before starting the risk assessment itself. Information gathered for a risk profile helps in deciding about the feasibility, depth and length of the risk assessment to be conducted according to available resources, legal and political considerations. A risk profile is similar to the scoping and screening stages used under other forms of impact assessment. Typically the risk profile includes a brief description of: the situation, foodstuff or commodity involved; information on pathways by which consumers are exposed to the hazard; potential risks associated with that exposure; consumer perceptions of the risks; the distribution of possible risks among different population groups; and current control measures. The risk profile is considered to be a responsibility of risk managers but in practical terms is primarily developed by risk assessors or others with specific technical expertise, and finally discusses and agreed by managers (FAO/WHO 2006).

In the field of food safety (and other fields of public health), specific differences in the procedure to conduct a risk assessment are mainly related to the type of hazard (i.e., chemical, biological, or physical hazard), the exposure scenario (i.e., known hazards versus emerging hazards, technological issues, complex hazard pathways such as for antimicrobial resistance) and the time and resources available. One of the most relevant issues refers to the different nature between chemical and biological hazards. The first ones are considered to enter in the food chain as part of row ingredients or through very concrete processing steps (i.e., additives or packaging migrants), remaining stable after the point of introduction, and causing mainly chronic health effects with some exceptions as potential acute health effects related to pesticide exposure. On the contrary, biological hazards are extremely ubiquitous and can radically change over time, growing, declining, or dying before a food is consumed. They cause normally acute health problems from a single edible portion of food, and generate a wide variability in health response (FAO/WHO 2006).

Risk Assessment Outputs

Results from risk assessment can be expressed in qualitative or quantitative terms with various intermediate formats.

Qualitative risk assessments outputs are the quickest to be obtained, but their value could be controversial for being rather subjective. Nonetheless, this approach could be quite useful depending on the context. They can be obtained by creating matrix that assigns risk ratings (low, moderate or high) to each one of the parameters affecting risk (likelihood of exposure, severity of the associated health outcomes, vulnerability or susceptibility of the population). A basic problem is that the three descriptors (high, medium, low) are often inadequate, and it is necessary to introduce some kind of numerical ranking for each category. The qualitative assessment outputs require even do of an extensive understanding of all the parameters affecting risk, reliable and accurate data about each factor, as well as a predefinition of the criteria used for assigning weight to each parameter (FAO/WHO 2006). An example of how to apply this approach is proposed by Fletcher (Fletcher 2005) for the field of fishery management. Traditional methods to incorporate expert knowledge in these circumstances and improve the quality and transparency of final qualitative outputs, include the Delphi method, the nominal group approach, focus groups, scenario analysis, rational consensus, self-scoring, collective scoring, surveys and questionnaires, interviews and case studies, among others.

In quantitative risk assessments, the outputs are expressed numerically, either in deterministic or probabilistic terms. The former used numerical point values (generally the mean or the 95th percentile value) for each parameter contributing to the risk (i.e., concentration of a chemical in a specific environmental media; the average daily consumption of drinking water, average body weight of the affected population, etc.), to generate a single risk estimate. Usually choices are the values that represent the most likely value, or alternatively values that capture the so called worst case situation or "worst case scenario" (i.e., the highest environmental concentration of a pollutant that population might be exposed to, or dietary exposures for frequent consumers). Using most likely values may be sufficient if the variability affecting most of the parameters is low, and the problem is well characterized. The use of a worst case scenario is more protective but could also lead to an unrealistically overly conservative output, of difficult applicability in adopting risk management options according to available resources. Deterministic techniques have been for years the approach most widely applied in risk assessment involving chemical hazards.

In the probabilistic approach the input values are distributions, and the final output is a range of possible scenarios of risk (characterized by a probabilistic distribution too), informing also about the variability and uncertainty associated with the calculated risk estimate. These two terms are often interchanged but they are not equivalent in the risk assessment process. According to the NRC, *uncertainty is the lack of precise knowledge as what the truth is, whether qualitative or quantitative* (NRC 1994 cited by Ricci 2006), for example because inadequate data exist, or because the biological phenomena involved are not well understood (FAO/WHO 2006; IPCS 2008). Risk assessors should provide an explicit description of uncertainties in the risk estimate and their origins, including a description of how assumptions may have influenced the final outputs. *Variability* describes the *range of possible*

values for any measurable characteristic inherent of a population, inasmuch as people vary substantially in their exposures and their susceptibility to potentially harmful effects of the exposure (NRC 2009). Variability cannot be reduced, but it can be better characterized with improved information.

The probabilistic modeling is considered to address more effectively and realistically the characterization of risk, but it demands larger resources and data, being more difficult and complex to be applied. It is increasingly used for the risk assessment of biological hazards.

A more exhaustive description of methods available for quantitative health risk assessment is described in Chap. 5 of this book.

Epidemiological Approach for Health Risk Assessment

A slightly different approach used in public health for risk assessment considers this process as the *systematic evaluation of changes in the population health resulting from modifying the distribution of population exposure to a risk factor or a group of risk factors* (Murray et al. 2003; WHO 2004). The major difference with previously reported procedures refers to the risk estimates which are not presented in terms of absolute risk (yes/no), excess risk (i.e., 3–4 times higher risk), or added risk. The so called *comparative quantification of health risk assessment* involves calculating the *population attributable risk*, or where multilevel data are available, *potential impact fraction (PIF)*, defined as the proportion of future burden of disease or injury that could be avoidable if current or future exposure levels to a risk factor or group of risk factors are reduced to hypothetical scenarios. Maldonado and Greenland (2002) and Murray et al. (2003) refer to those scenarios as *counterfactual*, and they imply a reduction in the distribution of a risk factor in the population to a theoretical minimum level (zero or as low as possible), or to a better achievable level (i.e., by 5, 10, 20, or 30 %). The counterfactual approach is considered more useful for policy-makers than the binary categorization into "exposed" and "non-exposed" which can substantially underestimate the importance of the continuous risk factor–disease relationship. The final avoidable burden of disease would be obtained by multiplying the total disease burden for the population (in deaths, hospital admissions or other metrics) by the PIF (Murray et al. 2003; WHO 2002, 2004). Those results could also be combined with cost-benefit analysis techniques to present results both in terms of health impacts and economic terms, of greater utility for policy-makers.

In summary the key methodological steps required are:

(a) Choice of most relevant health endpoint in terms of consistent definition, impact, strength of evidence of relationship with studied risk factors, and availability of baseline occurrence rates
(b) Identifying the population at risk (overall and/or susceptible groups)
(c) Selection of exposure indicators and study area for exposure assessment

(d) Definition of exposure scenarios
(e) Choice of the most suitable exposure–response function (i.e., relative risk for a given change in exposure) obtained from a systematic revision of the scientific literature that best fit to the studied population and exposure scenarios

The epidemiological health risk assessment approach has been a main focus of WHO early work on environmental health risk assessment and comparative burden of diseases (WHO 2000, 2002, 2004, 2009). This procedure has also been applied in several projects focused on the assessment of the health impacts related to a group of risk factors such as certain ambient air pollutants (Hurley et al. 2005; Pascal et al. 2013) or other environmental stressors (Prüss-Üstün et al. 2003; Hänninen and Knol 2011) or lifestyle risk factors (Soerjomataram et al. 2010; Lim et al. 2012).

The use of the terminology "health impact assessment" to refer to this methodology has created some misunderstanding and confusion with a much broader concept of the assessment of potential health impacts of a policy, programs or project on the health of a defined population, which will be described later in this chapter.

Improving Risk Assessment Procedure

The application of risk assessment has been increasingly extended to new issues and far-reaching public health and environmental questions as the scientific evidence and analytical techniques improved through time. However, its credibility is being challenged. Risk assessment findings have been accused of being unnecessarily complex sometimes, and not well connected to the needs and demands of the decision-making process. Furthermore, the lack of adequate procedure for involving all stakeholders at appropriate point in the risk assessment process has been identified as a pitfall that reduces reliability and transparency to the outputs (Montage 2004; Schreider et al. 2010).

The NRC's *Science and decisions: Advancing Risk assessment* (NRC 2009) provides recommendations for the improvement of the technical aspects and utility of risk assessment. Some of the most relevant suggestions, from a decision-support perspective, refer to:

- Better engagement in formative stages to the questions formulated by decision-makers, planning and designing risk assessment to evaluate the merits of different risk management options, rather than making of the risk assessment an end in itself. In this way, it is suggested to enclose the Red Book's paradigm (NRC 1983) into a new framework with enhanced problem formulation and scoping, and detailed definition of the required depth of the scientific analysis.
- The need to move from a narrow scope involving a single cause–effect pathway (i.e., a single chemical and a single adverse effect) to a more holistic assessment addressing risk posed by multiple stressors throughout multiple pathways.

- The level of detail for characterizing uncertainty and variability within the risk assessment process should be planned from the beginning, adjusting its complexity to the decision-making needs.
- It is also suggested to establish a formal process for stakeholder involvement throughout all stages but with time constraints to ensure that decision making schedules are met.

Similar developments can be observed in Europe: the European Commission is aware of the need for a new conceptual framework in risk assessment which should be an "*exposure-driven, flexible, tiered approach, drawing continually on advances in technology and scientific understanding of biology, which meets the needs of stakeholders*" (EU 2012, pp. 76). Currently, a public consultation on the discussion paper addressing the new challenges for risk assessment is under way.

Many of the proposed changes match with the evolution of the concept of health previously described.

Health Impact Assessment

The Gothenburg consensus paper defined Health Impact Assessment (HIA) as "a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population" (WHO Europe 1999). HIA intends to assist decision makers by providing a set of evidence-based recommendations on the causal pathways that link the different possible scenarios related to the implementation of a policy to potential health outcomes through a set of upstream health determinants and downstream risk factors (Kemm 2001, 2007; Joffe and Mindell 2002, 2006; Metcalfe and Higgins 2009). Its ultimate goal is to support the development of healthy policies by adjusting the design or adding new components to original proposals that maximize health gains, and minimize negative outcomes and health inequalities (Joffe and Mindell 2005; Mindell et al. 2008; Harris-Roxas and Harris 2011).

The most widely current practice of HIA takes as a reference the social view of health and equity, which as described above, gives a great importance to health determinants linked to interventions from non-health sectors (i.e., economy, agriculture, housing, occupation, transport), and to major equity indicators (gender, ethnicity and social class) (Metcalfe and Higgins 2009; Solar and Irwin 2010). In this way, HIA has been considered as a promising tool for promoting an effective implementation of the HiAP strategy, as well as for addressing potential health inequalities that might arise from a proposal (European Commission 2007; Wismar et al. 2007; WHO-Government of South Australia 2010; Harris-Roxas and Harris 2011; McQueen et al. 2012; Kemm 2013). Furthermore, HIA intends to promote coordinated cross-governmental actions, and a better understanding of the decision making process, adding transparency and democracy by involving other stakeholders (Kemm 2007; Salay and Lincoln 2008).

HIA Categorization and Forms

There is a broad variety of forms in which HIA is undertaken in practice. To categorize these forms, different criteria have been used (see Table 2.1). Some of those conditions refer somehow to technical aspects such as kind of intervention, its extension or complexity, the spatial scale to which it is applied, timing for conducting the HIA, or the methodology used. One of the critical points discussed for long refers to the appropriateness and utility to conduct concurrent or retrospective HIA. Those approaches although interesting from a scientific point of view, allowing gathering evidence for improving future HIAs, are late in providing useful information to the decision-making process. Therefore, there is a broad consensus that HIA should be performed preferably prospectively (Kemm 2001, 2013).

Cole et al. (2005), and Harris-Roxas and Harris (2011) proposed two different ways for categorizing HIA, the former based on the diverse origin of HIA, and the second on the purposes for which HIA is been conducted. Both proposals, complementary to a certain extent, allow a better understanding of the existing forms of HIA, and also identify major challenges to build capacity for a larger HIA implementation in the future.

Table 2.1 HIA characterization according to different criteria

Criteria	Type of HIA[a]
Type of proposal	Policies/programs
	Projects
Level of application	Supranational
	National
	Local
Extent	Desk-top
	Rapid
	Comprehensive
Health's model	Broad
	Tight
Timing	Prospective
	Concurrent
	Retrospective
Origin	Quantitative/analytic approach
	Participatory approach
	Procedural approach
Purpose	Mandated
	Decision-support
	Advocacy
	Community-led

[a]Cole et al. 2005; Joffe and Mindell 2005; Davenport et al. 2006; Mahoney et al. 2007; Kemm 2000, 2007; Veerman et al. 2005; Mindell et al. 2008; Bhatia and Werham 2008; Bhatia and Seto 2011; Harris-Roxas and Harris 2011

According to Cole et al. (2005), variations in HIA practice is very much related to the different fields from which they were promoted, detailed as follows:

- The "quantitative/analytic approach" strongly linked to the risk assessment framework applied mostly in the field of environmental health, but also in toxicology, epidemiology, engineering, economics and food safety. As described previously, this approach used for a long time a biomedical health model involving a single cause–effect pathway, although more recently HIA practitioners from those fields are considering multiple stressors and health outcomes, including some equity analysis. The functionalities of this approach from the decision-makers' perspective are: (1) the possibility to compare management alternatives (see previous description for *counterfactual scenarios*), and (2) its apparent objectivity in spite of the fact that it incorporates numerous assumptions. However, not all important health determinants and health outcomes can be measured, so the final picture in terms of health impacts provided by this approach is frequently quite partial, and responds to very specific purposes (i.e., alternatives for water treatment; defining maximum exposure values for air pollutants). Other limitations of this approach are quite similar to the ones already reported for risk assessment; basically its high cost, high demand of time and data, and its little stress on public participation procedures. Some examples of this approach were reported by Cole et al. (2005), Veerman et al. (2005), and Bhatia and Seto (2011).
- The "participatory approach" grounded on the Ottawa Charter's principles (WHO 1986), incorporates a more holistic health model, where all major causal pathways linking policy options, upstream health determinants, and health outcomes are tried to be identified in the assessment process. Under this framework the key input for analysis is the information provided through stakeholder participation, using mostly qualitative methodologies. This approach is considered to bring greater democratization and transparency to the decision-making process. However, the qualitative nature of the information generated makes more difficult the comparison among policy options, and also, depending on the context, is given less legitimacy for claiming changes in formulating a policy. Examples can be found in the USA (Dannenberg et al. 2008) as well as the extensive practice developed in European countries (Cole et al. 2005; Metcalfe and Higgins 2009; Kemm 2013).
- The "procedural approach" is coupled to the Environmental Impact assessment (EIA), a process legally binding for many countries worldwide that intends to ensure that environmental considerations (including social and health effects) are explicitly addressed and incorporated into the development of certain large projects, such as a dam, a motorway, or the construction of a factory (Salay and Lincoln 2008). The potential barriers and opportunities for integrating HIA within EIA process are still challenging tasks (Bhatia and Werham 2008). The existence of methods broadly disseminated and understood is proposed to ensure a relatively easy, transparent and reproducible manner to conduct HIA. On the contrary, some authors claimed that health considerations in this context have received only isolated attention, and that its emphasis on bureaucratic expediency

are at the root of many of its limitations (Cole et al. 2005; Lock and McKee 2005; Martin-Olmedo 2013).

According to Harris-Roxas and Harris (2011), the use alone of the possible HIA's origin as criteria to classify HIA practice, only leads to futile disagreements and conflicts among practitioners from different fields who claim the primacy of their approach, under-evaluating other disciplines. These authors proposed a typology of four different forms of HIA (see Table 2.1) based primarily on the purpose for which HIA might be undertaken, and also on its origin, the values underpinning the assessment, who should be conducting the assessment and, very important, on the learning that takes place through the process of conducting an HIA (technical, conceptual, and social learning). Those different forms are not totally exclusive from each other, existing in practice some overlaps between different categories (i.e., between advocacy and community-led HIA).

Procedure for HIA

There is no a single correct procedure of HIA as it can be applied to different types of decisions (from international policy to local projects), and a wide range of topics. The appropriate procedure varies depending on the framework and the purpose for which HIA is undertaken (Kemm 2007; Mindell et al. 2008; Harris-Roxas and Harris 2011). Different methodologies are proposed for characterizing the impacts, ideally combining multidisciplinary approaches which involve quantitative and qualitative techniques from a broad variety of academic domains (Joffe and Mindell 2005, 2006; Kemm 2007). Even so most of the different approaches share a five stage procedure with some variations in the terminology. Those phases are generally described (Cole et al. 2005; Joffe and Mindell 2005; Kemm 2007) as:

- *Screening*: a judgment on the added value and feasibility for conducting an HIA on view of the preliminary assessment of potential health impacts of an intervention. It main purpose therefore is to filter out proposals that do not need of a HIA because the impacts on health are either too obvious or not relevant. Screening implies a systematic process using a set of criteria usually listed in a checklist or algorithm, a rapid systematic review of the literature, and if necessary, the consultation to experts and affected stakeholders.
- *Scoping*: it sets the boundaries or term of reference for the HIA; this means a detailed roadmap of the analysis to follow, specifying the concerns of the decision makers and possible policy scenarios under evaluation, the causal pathways to be addressed (from policy to upstream health determinants, risk factors, and health outcomes), methodological aspects (depth of the assessment, geographical and time boundaries, availability of data, methods with equal recognition to qualitative and quantitative approaches), resources, and timetable. A steering committee is established in the scoping part, and the involvement of stakeholders as well as public is clarified.

- *Assessment of impacts*: also known as appraisal or risk assessment is the main stage which clarifies the nature and size of the health impacts likely to result from the scenarios related to a proposed policy. Differential distribution assessment of those impacts in the community is also an important task, although data required for this evaluation is not always readily available, and results are frequently controversial. As described before, this stage is being used wrongly in some context as synonymous of "health impact assessment" by itself. More detailed information on methodological aspects related to this stage, especially about quantification approaches, is developed in Chap. 5 of this book.
- *Reporting to decision-makers*: about the results of the assessment, and suggesting possible actions (including the no action option) for improving the intervention if necessary. The main content of the report should also be presented to all stakeholders who have participated in the process. It is very important that the timeframe for submitting this report meets the schedules of the decision making process. Communication skills are crucial at this stage, being necessary to adjust the language and format of the report to the audience needs.
- *Monitoring and evaluation*: depending on the approach it might include the following aspects: (1) evaluation of the HIA process (a mechanism of quality assurance in terms of planned outputs, cost and equity, and a source of learning for improving future practice); (2) monitoring the acceptance of recommendations (a way to analyze the effectiveness of the HIA process in improving the formulation of healthy policies); and (3) the outcome evaluation, monitoring the predicted impacts once the proposal has been implemented. This last aspect is considered by some authors as a complete different discipline called "policy evaluation".

A set of links to get access to a variety of HIA methodological guidelines, and practical experiences are listed in Table 2.2.

HIA Outputs

The evidence of impacts obtained from different sources at different stages of the HIA process can be both qualitative and quantitative, and include published literature, local data, and stakeholder's experiences (Joffe and Mindell 2005).

This evidence can be presented in different formats. Matrices are visual tools very extensively used for summarizing and structuring the evidence of potential health impacts in a qualitative way. In those matrices, the information gathered refers to:

a. Main health determinants and health outcomes affected;
b. The direction of change (+ if it is a health gain; or – if the impacts means a loss);
c. The severity of the impact (more or less signals of positive or negative depending on the scale of the impact) (Abrahams et al. 2004)

Table 2.2 HIA resources: methodological guidelines, and practical experiences

Name (URL)
WHO HIA Portal (http://www.who.int/hia/en/)
The HIA Gateway (part of Public Health England from 1 April 2013) (http://www.apho.org.uk/default.aspx?QN=P_HIA)
Centers for Disease Control and Prevention (CDC), Atlanta, USA—HIA resources (http://www.cdc.gov/healthyplaces/hiaresources.htm)
Institute of Public Health in Ireland (http://www.publichealth.ie/hia)
New Zealand Ministry of Health (http://www.health.govt.nz/our-work/health-impact-assessment)
Scottish Health Impact Assessment (HIA) Network (http://www.healthscotland.com/resources/networks/HIAresources.aspx)
Wales Health Impact Assessment Support Unit (WHIASU) Web site (http://www.wales.nhs.uk/sites3/home.cfm?orgid=522)
UCLA HIA-Clearing House—HIA-CLIC (USA) (http://www.hiaguide.org/)
CREIS (HIA portal in Spanish), Escuela Andaluza de Salud Pública (Spain) (http://www.creis.es/)
Austrian HIA Web site (HIA portal in German) Gesundheit Österreich (GÖG) (http:// www. goeg.at/)
Swiss HIA Portal (in French and German language), EIS association/GFA Verein (http://www.impactsante.ch/)

Causal pathways diagrams are also a visual way of presenting the multicausal relationships between an intervention and health effects. Each political option, through separate causal pathways, can be considered as different exposure scenario affecting a variety of health outcomes. Some of these causal relationships can be characterized by a function, and its combination may result in some modeling and quantitative outputs. However, very rarely it is possible to quantify the entire model (Joffe and Mindell 2002, 2006; Abrahams et al. 2004; Metcalfe and Higgins 2009)

A number of different quantitative approaches can be used to estimate the changes of the health status of the population due to an intervention. This topic is more extensively developed in Chap. 5 of this book.

Policy Evaluation

Policy evaluation is conceived as a discipline aiming to characterize the results of a policy or any other intervention during or following its implementation rather than predicting in advance potential impacts. This is the most critical difference from the tools previously described, risk assessment and HIA, both focusing mostly in improving policy formulation prior its implementation.

As reference guidance we highlight the H.M. Treasure' 2011 report *The Magenta Book. Guidance for evaluation,* which provides standards of good practice in conducting evaluations, and seeks to meet the specific and practical needs of policy makers and analysts working in public policy at all levels (local and national). According to this guidance a deep understanding of how and why policies work is essential in developing more effective and efficient policies in the future, allowing reinvestment or resource savings.

Policy evaluation is an objective process based on quantitative and qualitative techniques which encompasses three dimensions: (1) "process evaluation" accounting for all aspects related to whether a policy is implemented as intended; (2) "impact evaluation" referring to whether an intervention is effective in meeting its objectives, and (3) "economic evaluation," which compares the benefits of a policy and its cost.

Conclusions

The overview provided in the present chapter has shown that risk assessment and HIA are both valuable tools in supporting the decision-making process, sharing principles and approaches, but with important differences and particularities derived mainly from their origins and evolution through time.

Both frameworks are meant to be objective and systematic processes that intend to provide a set of evidence-based recommendations for the improvement of populations' health in the design of polices and interventions. Other attributes such as being transparent, science-based, well-planned, fully documented, open to participation or independent to the decision making process itself are also common values to both processes under current practice.

Risk assessment, having its roots on environmental health, used for long a biomedical health model involving a single cause–effect pathway which focuses on the relationship of single proximal risk factor and health outcomes, using mainly quantitative techniques for characterizing the impacts. Through time we have seen how the process has been reformulated, incorporating a more holistic approach, considering qualitative techniques, placing more emphasis on the early stage of planning and designing (scoping) to better adapt to questions formulated by risk managers, and improving the involvement of stakeholders.

HIA, linked from its origin to the strategy of HiAP, gives a great importance to health determinants linked to interventions from non-health sectors, adopting as a reference the social view of health and equity. The multidisciplinary approach needed for its compliance has not always been a reality, with confrontations from practitioners from different disciplines who claimed that the emphasis should be placed in one or other methodology (quantitative versus qualitative), when in fact all of them are necessary and/or complementary. Some misunderstanding have arisen regarding the appraisal stage of the process, also named risk assessment, and considered as "health impact assessment" in itself in some contexts.

A current debate is focusing on the convenience for integrating HIA into other forms of impacts assessment (i.e., environmental impact assessment). Enthusiasts of HIA claim that other forms of impact have paid only isolated attention to health considerations so far, and consider that HIA needs to be undertaken independently.

Still, application of risk assessment principles to policies and conduct of health impact assessment of policies is a rather complex and time consuming task. The following two chapters review experience from 10 top-down (policy to health

effect direction) and 7 bottom-up (from health effect to policies direction) policy risk assessment case studies coming from ten countries with the aim to develop a methodological guidance for policy risk assessment within or outside HIA.

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