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Review Article

Definitions of Risk in Health Surveillance: Integrative Review

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ABSTRACT
It is argued that potential risk, understood as the possibility of occurrence of an event, is the most adequate definition of risk for Health Surveillance. This integrative review analyzes the definitions of risk and identifies the purposes of using potential risk within the scope of Health Surveillance. Searches were carried out on a legislation database and on four other databases. A theory and a typology of risk supported the categorization. 14 normative acts and 20 articles were selected. The 70 definitions of risk were grouped into categories: probability of an event; probability and scenarios, consequences or severity of these; uncertainty; possibility of loss; event or consequence and uncertainty about the objectives. The limitations of some definitions were pointed out, such as the difficulty of calculating the probability of events. There are divergences between articles and normative acts regarding the terminology adopted to refer to risk. The definitions are composed of diverse terms, which cannot always be differentiated. Only one article investigates the meanings that professionals attribute to risk. Potential risk, an expression that has different definitions in Brazil and Russia, is used mainly to standardize risk assessment. A convergent effort is needed to intensify the use of the Brazilian theoretical definition attributed to potential risk and to minimize the variety of terms used in the definitions of risk.

Keywords: Health Surveillance, Review, Risk, Risk Management.

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INTRODUCTION

Technological development has fostered deliberation on risks among various institutions, such as the Food and Drug Administration (FDA) and the Pan American Health Organization (PAHO). In Brazil, there is the National Health Surveillance System (SNVS), which is coordinated by the National Health Surveillance Agency (ANVISA).

Health Surveillance (HS) is a field of knowledge and practices aimed at managing the risks associated with the production and consumption of health-related products and services[1]. As these objects are socially contextualized, definitions of risk that use a probabilistic approach are considered inadequate.[1] To overcome these probabilistic approaches, it is recommended to take into consideration the potential risk, defined as "[...] the possibility of occurrence of a health problem [...]".[1,2]

Despite such recommendation, it has been pointed out that there is no consensual understanding of risk within the Brazilian SNVS.[3] This can cause problems in regulatory activities because defining risk, in addition to being a semantic exercise, influences risk management.[4,5]

With the increase in the global circulation of goods, there is a need to align the requirements adopted by countries.[6] The results from the present study are expected to contribute to this regulatory convergence.

The polysemy of risk drives investigations that explore the statements used to define it. Aven[4] developed a typology composed of categories of definitions. According to Boholm and Corvellec,[7] risk consists of a relationship between a risk object and an object at risk. Guided by these approaches and given the importance of potential risk for the regulation of health-related products and services, this study aimed to analyze the definitions of risk and identify the purposes of using potential risk in the literature on HS.

MATERIALS AND METHODS

This is an integrative review[8-10] guided by the following research questions: what are the definitions of risk used in the literature to addresses HS activities? Which terms are used in these definitions and which types of risk do they refer to? What are the purposes of using potential risk?

The search for definitions of risk took place in two stages. Stage 1 involved searches on Resolutions of the Collegiate Board of Directors (RDC) - normative acts used by ANVISA to regulate products and services - whereas Stage 2 explored the scientific literature (Figure 1).

Each stage consisted of search, pre-selection and selection procedures carried out independently by two evaluators with expertise in HS from September 2020 to February 2021. In case of disagreement about the results, the recommendations of a third evaluator were accepted. This study meets the criteria established for literature reviews in general[10] and for integrative reviews.[8]

Stage 1

The legislation database available on the ANVISA website[11] was used as a source of information. The study included RDCs currently in effect. Documents that did not deal with requirements for the regulated sector were excluded.

Filters related to the inclusion criteria were activated for the search and descriptors were not used. The exclusion criterion was applied during pre-selection, which consisted of the reading of the summaries of each RDC. After reading the pre-selected RDCs in full, only those with definitions of the term risk were selected (Figure 1).

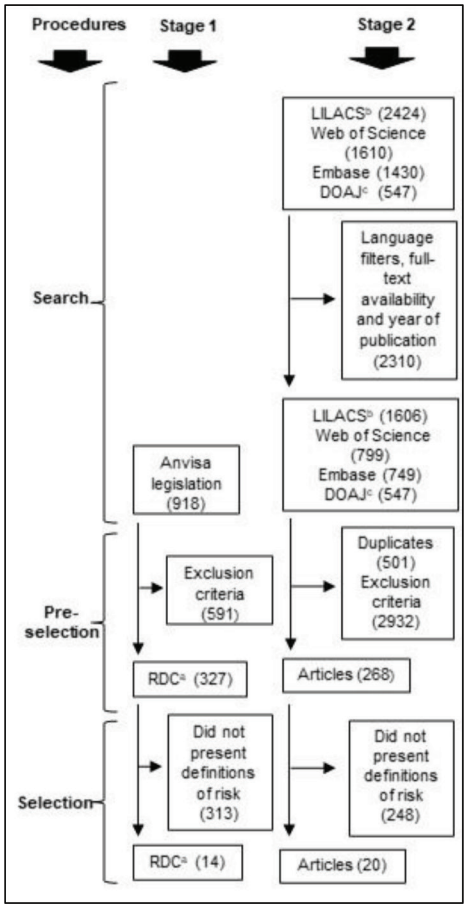

Figure 1: Flowchart of literature selection process.
[a]Resolutions of the Collegiate Board of Directors. [b]Latin American and Caribbean Health Sciences. [c]Directory of Open Access Journals. (at column width)

Stage 2

The following databases were searched: Web of Science and Embase, accessed via the Coordination for the Improvement of Higher Education Personnel (CAPES) Journal Portal; the Latin American and Caribbean Health Sciences Literature (LILACS), accessed via the Virtual Health Library (VHL); and the Directory of Open Access Journals (DOAJ). The last two were chosen because of their regional scope and open access, unlike the first ones.

Search strings were designed using the following controlled vocabularies: Health Sciences Descriptors (DeCS), Medical Subject Heading (MeSH) and Emtree. Descriptors related to the activities developed by HS[12,13] were extracted from the models that address means of work (sanitary inspection, supervision and technologies) and evaluation of actions (management; regulation; sanitary control; health risk monitoring; health information, communication and education). Two strings were designed and used according to the database (Table 1). For searches on DOAJ and LILACS, the search string also included Spanish and Portuguese terms.

Some inclusion criteria applied in this stage were: the document should be a research article addressing activities developed within HS (a term specifically used in Brazil) or another governmental organization (in the case of other countries) for the regulation of health-related products or services. The full text of the document should be available and written in Spanish, English or Portuguese. The documents should have been published from 1999 onwards. This time limit criterion was used because ANVISA was created that year. Exclusion criteria were: duplicates, articles focused on specific diseases or injuries and that defined tolerance limits for environmental agents, epidemiological surveys and investigations, reviews, theoretical essays, debates and editorials.

Filters related to the inclusion criteria were activated during the search when available. Exclusion criteria were applied during pre-selection, which consisted of the reading of titles and abstracts. After reading the pre-selected articles in full, only the documents that used definitions of risk remained in the selection stage (Figure 1).

Table 1: Search strings used for each database.

Database	Search string
Web of Science and Embase	(Legislation OR "Dental Legislation" OR "Food Legislation" OR "Hospital Legislation" OR "Nursing Legislation" OR "Pharmacy Legislation" OR "Veterinary Legislation" OR "Labor Legislation" OR "Labour Legislation" OR "Drug Legislation" OR Regulation OR Regulations OR "International Health Regulation" OR "International Health Regulations" OR "Health Regulation" OR "Health Regulations" OR "Legal Aspect" OR "Medical Device Regulation" OR "Medical Device Legislation" OR "Medical Equipment Regulation" OR "Safety Management" OR "Safety Precaution" OR "Safety Protection" OR "Safety Regulation" OR Control OR "Control System" OR "Quality Control" OR "Quality Assessment" OR "Quality Assurance" OR Monitoring OR Information OR "Information Dissemination" OR "Health Data" OR Technology OR "Medical Technology" OR "Biomedical Technology" OR Education OR "Health Science Education" OR "Health Sciences Education" OR "Health Literacy" OR "Health Education" OR "Sanitary Supervision" OR "Sanitary Control") AND (Risk OR "Risk Factor" OR "Risk Factors" OR "Relative Risk" OR "Risk Predictors" OR "Risk Predictor" OR "Risk Assessment" OR "Risk Analysis" OR "Risk Evaluation" OR "Risk Management") AND ("Sanitary Surveillance" OR "Sanitation Surveillance" OR "Health Care Organization" OR "National Health Organization" OR "National Sanitary Vigilance Agency" OR "Health Regulatory Agency" OR "National Agency For Health Monitoring" OR "National Health Surveillance Agency" OR "Health Surveillance Agency" OR "Health Surveillance" OR "Public Health Surveillance" OR "Sentinel Surveillance" OR "Health Care Surveillance" OR "Healthcare Surveillance")
DOAJ[a] and LILACS[b]	"Sanitary Surveillance" AND Risk AND (Legislation OR Regulation OR Regulations OR Control OR Monitoring OR Information OR Technology OR Education OR "Sanitary Inspection" OR "Sanitary Supervision")
	"Vigilancia Sanitaria" AND Riesgo AND (Legislación OR Regulación OR Regulaciones OR Control OR Monitoreo OR Información OR Tecnología OR Educación OR "Inspección Sanitaria" OR "Fiscalización Sanitaria")
	"Vigilância Sanitária" AND Risco AND (Legislação OR Regulação OR Regulações OR Controle OR Monitoramento OR Informação OR Tecnologia OR Educação OR "Inspeção Sanitária" OR "Fiscalização Sanitária")

[a]Directory of Open Access Journals. [b]Latin American and Caribbean Health Sciences. (at full page width)

Data Analysis

The selected sources were stored in a database on NVivo version 11. After that, data analysis was guided by a data analysis spiral involving stages of organization, classification, interpretation and representation of data.[14]

The sources were classified according to type (normative act; article), terminology used to characterize the type of risk, and purposes of using potential risk.

Definitions of risk were categorized according to Aven's[4] typology. The categories are: (A) probability of an event; (B) probability and scenarios, consequences or severity of these; (C) possibility of loss; (D) event or consequence; (E) uncertainty; (F) uncertainty about objectives; (G) expected loss value; (H) objective uncertainty; (I) consequences or their severity and uncertainty.[4] For the empirical categorization of origin, the definitions contained in RDC were considered normative (N), while those in articles were considered either (T) theoretical – when derived from referenced literature – or (P) empirical – when derived from results of studies. The identified definitions were coded using letters corresponding to these sub-categories.

The terms that appear in the definitions were grouped into the following analytical categories: quantitative; qualitative; events, consequences and severity of these; risk objects and objects at risk. Quantitative terms refer to the measurement of risk and qualitative terms denote the subjective rather than quantitative apprehension of risk.[4] The situations identified in the definitions were considered events or consequences related to risk.[4] Risk objects refer to the possible causes of risk and objects at risk represent what is threatened.[7]

RESULTS

The searches yielded 6,929 documents. Of these, 14 RDC and 20 articles were selected, with 70 definitions of risk identified (Figure 1).

Types of Risk and Purposes of Using Potential Risk

RDCs and articles use various terms to characterize the type of risk and their differentiation is not clear in some cases. For example, chemical risk[15] can also be a risk to public health,[16] while potential risk is presented as a synonym for "sanitary risk" and "health risk"[17,18] (Table 2).

Table 2: Categorization of the literature on Health Surveillance, 1999-2021.

Type of source	Author	Type of risk	Purpose of using potential risk
Normative acts	Brasil[15]	Chemical	NA
	Brasil[16]	For public health	NA
	Brasil[19]	Identified; potential	To classify an occurrence as suspicious
	Brasil[33]	Factor; to public health	NA
	Brasil[34]	To public health	NA
	Brasil[35]	Biological	NA
	Brasil[36]	Factor	NA
	Brasil[37]	...	NA
	Brasil[39]	...	NA
	Brasil[40]	...	NA
	Brasil[41]	...	NA
	Brasil[42]	...	NA
	Brasil[51]	...	NA
	Brasil[52]	...	NA
Articles	Leal and Teixeira[17]	Sanitary; Potential	To incorporate a concept of risk
	Popova, Zaitseva, May and Kiryanov[18]	Health; Potential	To classify activities based on the degree of risk
	Navarro, Costa and Drexler[20]	Potential	To develop a MARP[a]
	Silva, Vianna, Oliveira, Mosegui and Rodrigues[21]	Potential	To develop an inspection instrument
	Silva Júnior and Rattner[22]	Potential	To develop a MARP[a]
	Silva Júnior, Rattner and Martins[23]	Potential	To describe the situation according to the MARP[a]
	Silva Júnior and Rattner[24]	Potential	To describe the situation according to the MARP[a]
	Viterbo et al.[25]	Classic; Potential	To develop a MARP[a]
	Jesus and Lima[26]	Potential	To ratify the importance of potential risk
	César, Silva, Figueiredo and Laguardia[27]	Classic; Potential	To identify sanitary irregularities
	Ferreira[28]	Potential	To warn about rule breakers' safety
	Andreeva[29]	Potential	To classify activities based on the degree of risk
	Aroca and Guzmán[30]	...	NA
	Silva and Lana[31]	...	NA
	Marins, Ferreira and Jesus[32]	Sanitary	NA
	Freitas and Santos[38]	...	NA
	Barbosa and Costa[43]	...	NA
	Caldas[44]	...	NA
	Costa, Jorge and Donagema[53]	...	NA
	Janes and Marques[54]	...	NA

[a] Potential Risk Assessment Model. ... Uses only the term "risk". NA: not applicable. (at full page width)

Potential risk is used in the RDC[19] that defines it to qualify suspected unfavorable occurrences, a purpose that differs from those adopted by scientific articles. The first published article uses potential risk with the purpose of standardizing the risk assessment and describing the health situation in radiodiagnosis services.[20] Such intentions motivated other Brazilian studies carried out in facilities that generate waste[21] or that provide services such as hemotherapy[22-24] and food.[25]

The methodology used in these articles is supported by the fuzzy logic[21] or the potential risk assessment model (MARP).[20,22-25] Potential risk is also used to reaffirm its suitability for HS[17,26] and to highlight situations that must be modified.[27,28]

Different from previous approaches, two Russian studies described and evaluated the classification of economic activities according to the degree of potential risk.[18,29] The classification process considered the number of people exposed, the severity of the damages and the violation of regulations.

Colombia has also developed a model for the classification of activities.[30] This model differs from the Russian one in that it does not use the term "potential risk". In that case, the measurement of the degree of risk involves variables such as time elapsed since last inspection visit and complaints.

Definitions of Risk

Empirical, theoretical and normative types A, B, C and D definitions are similar. Only one study offers empirical definitions, which were obtained from professionals of the Brazilian SNVS.[31] Furthermore, no normative and empirical types E and F definitions were identified (Table 3).

The results show divergences regarding the understanding of potential risk, an expression for which there are three definitions. In the Brazilian context, there are two definitions: the theoretical one – possibility of occurrence of injuries, damages or events that affect health[17,20-28] – and the normative one – "unfavorable occurrence in which there is suspicion of association of risk with a given medication".[19] Although the latter keeps the notion of possibility due to the word "suspicion", its applicability is restricted to situations arising from the use of medications.

Expressed in a Russian article, the third way to define potential risk is: "a combination of probability, severity of damage to health and number of people influenced by the activities of an economic entity that violates regulations".[29] In using probability, this definition differs from the Brazilian ones, which are eminently qualitative.

Two studies[25,27] differentiate potential risk from classic risk, with the latter seen as being related to probability and the first seen as being related to possibility. In the DN definition, identified risk differs from potential risk due to the existence of adequate evidence of a relationship between an event and medication.[19]

"Health risk" is described by the CT definition, which is similar to the Brazilian theoretical definition of potential risk, but more specific as it indicates the risk objects.[32] The other definitions refer to other normative considerations of risk terminology: BN and risk for or to public health;[16,33,34] CN and chemical risk[15] and AN and biological risk.[35] Risk factor is defined as "variation statistically associated with the appearance of a disease or a health phenomenon [...]".[36]

Terms Used in Definitions of Risk

The definitions use terms whose differentiation is not always possible. For example, a carcinogenic potential[15] and a health phenomenon[36] can both be considered adverse events[37] (Table 4).

Types A and B definitions are quantitative, as they denote mathematical elements, such as probability.[38] Some definitions,[39-42] such as BN, use the words "combination" or "function" to relate the elements that compose them, but they do not specify how this relationship is quantified. However, in the theoretical dimension, the aspects that contribute to the risk and the relationship between them are specified by some studies, thus making it possible to measure the risk,[18-30] as in BT. The other categories of definitions are qualitative, as they feature terms expressed using a subjective connotation.

Events, consequences and severity of these generally refer to undesirable situations that threaten something valued. Some expressions, such as medications, are part of the HS context. Others denote a consequence itself or the cause of a future event. For example, production failure[31] can be understood as a consequence of an error, but also as the cause of an allergy. The term danger is used in some definitions[16,31,33,34,43,44] to denote threat of harm, as in DT.

Table 3: Typology of definitions of risk present in the literature on Health Surveillance, 1999-2021.

Defining category	Origin		
	(N) Normative	(T) Theoretical	(P) Empirical
(A) Probability of an event[a]	"Potential or effective probability of exposure to biological material originating from the worker, other people involved and the environment."[35]	"Probability of an adverse health event occurring in the presence of a certain factor."[38]	"It is the probability of occurrence of danger."[31]
(B) Probability and scenarios, consequences or severity[a]	"Combination of the probability of occurrence of damage and the severity of this damage."[39]	"Probability of health code violation multiplied by the damage associated with the violation and the size of the exposed population."[18]	"Probability, magnitude and exposure."[31]
(C) Possibility of loss[a]	"Mutagenic, carcinogenic and/or teratogenic potential."[15]	"Possibility of damage or injury, adverse health effect, related to procedures, products and services."[32]	"It is associated with the potential."[31]
(D) Event or consequence[a]	"Unfavorable occurrence for which there is adequate evidence of its association with a given medication."[19]	"Potential hazard or threat of harm or injury requiring health protection interventions"[44]	"It is any failure in the production chain"[31]
(E) Uncertainty[a]	...	"Uncertainty"[43]	...
(F) Uncertainty about objectives[a]	...	"Effect of uncertainty on objectives."[30]	...

[a] Aven's categories[4]. ...No definitions of risk were found. (at full page width)

DISCUSSION

In order to analyze the definitions of risk and identify the purposes of using potential risk, this review explored the literature on HS activities. Firstly, the following argument is provided to analyze the definitions. After that, we address the purposes of potential risk and the terms used in the definitions.

Table 4: Typology of the terms used in the definitions of risk present in the literature on Health Surveillance, 1999-2021.

Quantitative[a]	Statistical variation; probability; combination or function of probability; number of people[16,18,25,27,29–31,33-43,51,52,54]
Qualitative[a]	Potential; possibility; property; uncertainty; suspicion[15,17,20–28,31,32,43,44,53]
Events or consequences or severity of these[a]	Disease; health phenomenon; injury; damage; exposure; adverse, non-standard, detrimental or impactful situation, effect or something else; intoxication; danger; unfavorable occurrence; threat; adventure; relationship between person and product; skipping a procedure; unexpected outcome; perception of danger; mutation; cancer; teratogenicity; alteration; critical point; failure; exchange; international dissemination; violation of legislation[15,16-44,51–54]
Risk objects[b]	Biological material; medication; food; procedure; action; product; service; substance; economic activity; factor; production chain; element; object; local; environment[18,19, 28,29,31,32,35,38,42,44,52,53]
Objects at risk[b]	Health; environment; non-target species; worker; people; quality of life; professional; user[16,18,21-26,28,29,31–38,42,44,51–53]

[a] Adapted from Aven[4]. [b] Bolhom's and Corvellec's categories[7]. (at full page width)

The predominance of positivism and the epidemiological approach in the health field justify the adoption of types A and B definitions in the context of HS. These categories of definitions have distinct limitations. In epidemiology, assumptions that events recur in a serial manner and that morbidity has a homogeneous nature are pointed out by researchers as flaws inherent in the probabilistic approach.[45]

In the field of risk analysis, it is argued that type B definitions should detail how the relationship between the event and its consequence or severity is quantified.[5] However, with some exceptions, the definitions identified by this review, did not provide such details, which has also been observed by another study.[5]

It is also argued that type A definitions are flawed because they do not denote the consequences of the events to which they refer.[4] For example, if the probabilities of someone being exposed to two samples are identical, the risks of an accident are also equal when definitions such as AN are assumed. However, if one considers the fact that one sample also contains harmless microorganisms, while the other includes bacteria causing a potentially lethal infection, the consequences would allow classifying an accident with the second sample as a higher risk.

The previous example is an exception within the context of HS, which, in fact, is full of situations for which the measurement of probability is difficult[1] due to both the lack of knowledge of the causes and the conditions dependent on the contexts where the phenomena of interest occur.[2] In the real world, even if there is an estimated probability, one is never quite correct about this quantification.[46] Therefore, almost all decisions are made under uncertainty.[46]

With regard to qualitative definitions, type F is considered inaccurate as it does not include situations for which the objectives were not specified.[4] The same occurs with types D and E, which, respectively, do not allow us to infer the degree of risk and disregard its consequences or severity.[4] Furthermore, in the context of HS, it is generally not possible to accurately predict all events and consequences associated with a product or service, especially among those that have recently been approved for use. The absence of types E and F definitions in the normative and empirical dimensions demonstrates that some theoretically consolidated concepts are not prominent in the practical field.[47]

Type C definitions mention the possibility or potential of events in a condition of uncertainty and are hence considered the most appropriate for the analysis of risk in general[4] and in the context of HS.[1,2] Potential risk is also in this category, but it is unequally defined in Brazil[17,20-28] and Russia,[29] and its differentiation from other terms is not clear.[17,18] Therefore, there is a need to standardize definitions and terminology.

The standardization of risk assessment, which is the main purpose of using potential risk, is applicable to different dimensions. The Brazilian proposal, which features the element of possibility, has a specific dimension as it develops instruments for the inspection of particular objects,[17,20-22,24-28] whereas the Russian proposal,[18,29] oriented by probability, is broader in classifying economic activities according to the degree of risk.

In Brazil, the RDC[48] that regulates the classification of activities was not selected for this review as it does not provide a definition for the term risk – instead, it provides a definition of the degree or level of risk. Unlike the Russian[18,29] and Colombian[30] models, the Brazilian model does not detail how the classification criteria contribute to the degree of risk. It should be noted that the analysis of the effectiveness of these models goes beyond the objectives of this study.

Potential risk is also used in some articles to highlight health situations[27,28] and to reaffirm its suitability to the context of HS.[17,26] In contrast, RDCs have not yet taken the perspective of potential risk, with only one exception[19] that has been recently published. This conceptual and temporal mismatch of scientific production in relation to legislation can confuse professionals working in HS or in the regulated sector.

The quantitative and qualitative terms used in the definitions respectively relate to the quantitative or qualitative approaches taken by the definitions that include them.[46] Variations in the terms used in the definitions to characterize the type of risk are explained by the continuous reformulation of the definitions according to different perspectives.[7] Nevertheless, it is worth questioning whether this diversification is really necessary, as it can compromise the communication of risks.

Risk definitions also result from interpretations of the reality experienced involving aspects such as action, intentionality and decision.[7] Therefore, some terms in the definitions refer to situations and objects inherent in the context of HS. The literature also points to a confusion as to cause and consequence[47] because some terms refer to either one or the other. It should be noted that assertions based on natural language to the detriment of those involving mathematical elements are more appropriate as they lead to a better understanding among those interested and do not depend on adaptation to probabilistic theories.[49]

From a linguistic perspective, danger and threat are related to the source of an unwanted event.[47] In contrast, from a sociological approach, danger is characterized by the absence of intention, while risk and threat have positive and negative intentions, respectively.[50] This distinction should be considered in HS, as there are situations in which damage results from intrinsic characteristics of the object – positive intention – or from intentional alterations – negative intention.

Unlike the scientific production, the normative acts included in this review were restricted to the Brazilian context. However, this limitation does not diminish the importance of this study as the problems addressed herein are likely to happen in other countries.

CONCLUSION

In addition to definitions based on the probability or possibility of an event, the literature on HS uses other definitions that consider risk as events or consequences, uncertainties and uncertainties about the objectives. Because these definitions use terms that are not always differentiated, their simultaneous use can cause misunderstandings

that may interfere with risk management. The standardization of risk assessment is the main purpose of using potential risk, an expression that has different definitions. Some recommendations are proposed to contribute to the regulation of health-related products and services. First, there is still a need for a convergent effort to minimize the variety of definitions. Second, the theoretical Brazilian definition of potential risk[2] should be increasingly used, especially by RDCs. Finally, it is still necessary to investigate the definitions of risk adopted by health professionals and the population.

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