ARTICLE
https://doi.org/10.22239/2317-269x.01015

Strategy for prioritizing whistleblowing with potential risks related to health services

Estratégia para priorização de denúncias com risco potencial relativas a serviços de saúde

Rafael Fernandes Barros*

Benefran Júnio da Silva Bezerra

Agência Nacional de Vigilância Sanitária (Anvisa), Brasília, DF, Brasil

*** E-mail:** rafaelfbarros@uol.com.br

Received: Aug 6, 2017
Approved: Nov 17, 2017

ABSTRACT

Introduction: The Sanitary Surveillance of Health Services receives daily denunciations that refer to situations of risk that can hardly be measured quantitatively and attribute to some type of specific damage, in a context of great uncertainty. **Objective:** Considering such situations should be adequately addressed under the health risk paradigm, this work had as objective identifying notions about risk and its forms of analysis in the scope of Sanitary Surveillance of Health Services, as well as the existence of strategies and models in the analysis and treatment of denunciations. **Method:** An extensive literature review (through the Regional Portal of the BVS, databases SciELO and SciELO Books, and the journal *Visa em Debate*) was conducted. **Results:** Although the results point to a relatively recent discussion regarding the model of potential risk analysis as an operational concept for the field of health surveillance in health services, there is no description of strategies or models applied to the analysis or treatment of whistleblowing. Thus, it is discussed and proposed a strategy for the initial analysis of reports with potential risk, which seeks to bring minimally objective criteria, in a field marked by enormous subjectivity. **Conclusions:** We conclude by indicating that the presented strategy is an initial instrument for the management of whistleblowing that must be discussed and adapted to the reality and context of health surveillance agencies.

KEYWORDS: Potential Risk; Whistleblowing; Prioritization Strategy; Health Surveillance

RESUMO

Introdução: A Vigilância Sanitária de Serviços de Saúde cotidianamente recebe denúncias, que fazem referência a situações de risco, que dificilmente pode mensurar quantitativamente e ser atribuída a algum tipo de dano específico, em um contexto de grande incerteza. **Objetivo:** Tendo em vista que tais situações devem ser adequadamente abordadas sob o paradigma do risco sanitário, este trabalho teve como objetivo identificar noções sobre o risco e suas formas de análise no âmbito da Vigilância Sanitária de Serviços de Saúde, bem como a existência de estratégias e modelos na análise e tratamento de denúncias. **Método:** Foi realizada extensa revisão da literatura (por meio do Portal Regional da Biblioteca Virtual em Saúde, das bases SciELO, SciELO *Books* e também do periódico Visa em Debate). **Resultados:** Embora os resultados apontem discussão relativamente recente a respeito do modelo de análise de riscos potenciais enquanto conceito operativo para o campo da vigilância sanitária de Serviços de Saúde, não há descrição de estratégias ou modelos aplicados à análise ou tratamento de denúncias. Assim, discutimos e propomos uma estratégia própria para análise inicial de denúncias com risco potencial que busca trazer critérios minimamente objetivos em um campo marcado por enorme subjetividade. **Conclusões:** Concluímos ressaltando que a estratégia apresentada é um instrumento inicial para o gerenciamento de denúncias que deve ser discutida e adaptada à realidade e contexto dos órgãos de vigilância sanitária.

PALAVRAS-CHAVE: Risco Potencial; Denúncia de Irregularidades; Estratégia de Priorização; Vigilância Sanitária

INTRODUCTION

Sanitary Surveillance bodies receive daily whistle blowing reports from citizens and entities based on their *risk perception* in the various stages of the production-consumption cycle subject to sanitary surveillance. However, in order for citizens' channels of communication to be effective instruments of citizenship and consistently incorporated into sanitary surveillance technological practices, we need to systematize the analysis and treatment of reports aligned with Sanitary Surveillance instruments of action.

Sanitary Surveillance is one of the oldest public health practices. Its objective is to prevent the risks to the health of individuals and populations. Intermingled with social, political and economic matters, sanitary surveillance actions are fundamentally aimed at controlling real and potential risks to health, with an essentially protective nature, not only from damage, but also from risks[1].

In order to prevent risks, sanitary surveillance makes use of various intervention technologies through regulation, inspection, supervision, monitoring and others. Lucchesi[2], however, points out the need for reorientation of its practices through effective social control. In this sense, we can highlight that society's participation through whistleblowing to sanitary surveillance bodies indicates its own perception of risks, of the objects of sanitary surveillance control and of the actual or potential risks perceived by the whistleblower.

Thus, one of the main work processes carried out by the Health Regulation and Control Department in Health Services/General Management of Technology in Health Services (Grecs/GGTES) of the Brazilian Health Regulatory Agency (Anvisa) is the analysis and handling of reports received by different channels, like Anvisa's Ombudsman's Office, the Unified Health System's Ombudsman's Office, official communications, citizens' letters and internal Anvisa communications.

We should also note that sanitary surveillance actions in Brazil are developed based on the principle of political-administrative decentralization, under the terms of Law 9.782, of January 26, 1999[3]. Therefore, sanitary surveillance actions in health services, such as inspection, issuance of sanitary permits and the institution of an administrative proceeding to determine sanitary infractions in health services, are the responsibility of the local Health Surveillance bodies, according to the current Unified Health System's operating standards. Thus, the handling of whistleblowing reports received at Grecs/GGTES/Anvisa requires, in most cases, a coordinated inter-federation articulation.

At the same time, in order to have adequate health risk management, we need to prioritize the demands considered as having "greater risk", considering the political, regulatory and social implications of the issues raised and the operational capacity of the sanitary surveillance service. In this sense, it is important that the federal agency be able to coordinate this action with other entities in order to give "greater risk" demands faster resolution in the face of the various demands that involve sanitary surveillance bodies in various spheres.

The objective is not to fail to address some categories of whistleblowing reports, but to use strategies that, under the Health Risk paradigm, allow different approaches to different demands according to their potential to cause damage. That is a great challenge, since it is necessary to develop a rational strategy that is capable of ranking different degrees of priority - and suitable approaches - of the countless whistleblowing reports received by sanitary surveillance bodies every day. This should create a rationale based on the paradigm of risk control in order to bring minimally objective criteria to a very subjective field.

To get a picture of how difficult this may be, it is worth highlighting that the everyday work of the Sanitary Surveillance of Health Services often faces very particular risks, translated as situations that can generate damage before any outcome or health-related event occurs. On the other hand, when the whistleblowing points to rumors of infections or non-infectious adverse events, there are some approaches that - supported by epidemiological paradigms - are useful for the analysis and treatment of rumors concerning health events.

Most of the whistleblowing, however, refers to: situations perceived as risky by the whistleblower and relevant from the point of view of sanitary surveillance, unprecedented situations that rarely or never occurred in the past, which are often different from the epidemiological approach and the classical expression of risk as probability versus severity. This risk is extremely difficult to measure or apprehend precisely because there are no objective and clear criteria to adequately manage the reported situation. For example, what would be the risk of missing indicators in a sterilization process? What is the risk of a professional not wearing gloves in a particular procedure? Or, what is the risk of not doing proper maintenance of the equipment for laboratory analysis? Or not performing preventive maintenance on a mammography device? Thus, risk assessment mechanisms applicable to health services are generally poorly studied.

To support actions that corroborate a more technical approach, we have searched scientific literature to identify the various notions of risk and its forms of analysis in the scope of Sanitary Surveillance of Health Services, as well as existing strategies and models based on the risk paradigm and used in the analysis and handling of whistleblowing reports.

METHOD

First, along with the Virtual Health Library (VHL), we determined the Health Sciences Descriptors that best fit with the research objectives. These descriptors are summarized in Box 1, as well as their synonyms given by the VHL. We only used descriptors in the Portuguese language due to the specificity of the term and concepts related to "Sanitary Surveillance" within the Brazilian context.

Next, we selected the databases of scientific articles. We eventually chose the Regional Portal of the VHL - with dozens of bases, among them Latin American and Caribbean Literature

in Health Sciences (Lilacs), Medical Literature Analysis and Retrieval System Online (Medline), Scientific Electronic Library Online (SciELO) and SciELO Books, as well as the *Vigilância Sanitária em Debate: Sociedade, Ciência & Tecnologia* (*Visa em Debate*) journal - according to their relevance for Health Sciences, Public Health and Sanitary Surveillance. These virtual databases were accessed in August 2016 and, considering each database specification, we adopted the search strategy shown in Box 2.

This strategy produced 400 references in the SciELO databases, 785 references through the VHL and 47 in the *Visa em Debate* journal. We emphasize that there was no time restriction. After the search, we read the abstracts of the articles with the objective of selecting those that fit with the purposes of the research. Those that presented concepts or discussion about risks or that dealt with risk models and were related to public health and sanitary surveillance were included.

Subsequently, we excluded the articles that did not refer to sanitary surveillance or public health and dealt with the risk assessment of specific areas (such as the toxicological evaluation of molecules) or other sanitary surveillance-related matters (such as risk in food). Articles that did not directly address the objectives of this research were excluded, in addition to those with limited access or that were not available in their entirety.

With that in mind, five articles were selected from the SciELO and SciELO Books databases, five from the VHL and three from *Visa em Debate*. We withdrew duplicate articles considering that of the five VHL references, four were also on SciELO. Thus, nine articles were included in the review.

Box 1. Descriptors used in the literature review.

Descriptor	Synonyms
sanitary surveillance	sanitary police; sanitary control; competent sanitary surveillance body; sanitary surveillance master plan
risk	knowledge of risk
health risk	-
proportional hazards models	risk models

Box 2. Search strategy.

Database	Search strategy
SciELO and SciELO Books	1) risk AND health surveillance; 2) health risk; 3) proportional hazards models; 4) risk models.
VHL	1) "risk" AND "health surveillance"; 2) "health risk"; 3) "health surveillance" AND "proportional hazards models"; 4) health surveillance AND risk model; 5) "risk models" AND "health risk".
Visa em Debate	"risk".

RESULTS AND DISCUSSION

The texts revealed several peculiarities regarding sanitary risks in the Sanitary Surveillance of Health Services. However, the literature does not present models or strategies based on a risk approach applied to the analysis or handling of whistleblowing reports related to health services, hence the need to develop a strategy of our own, supported by important questions that emerged and will be described below.

Risk and its conceptions

As discussed in the literature, risk can be considered as one of the founding elements of modernity, playing the most prominent role in sanitary surveillance, since it guides all the practices under its responsibility[4]. However, despite its enormous importance, there is no consensus on its approach or on its meaning, since the term is polysemous, although it is historically associated with the idea of predicting an unwanted future event[5,6].

This breadth of meanings of risk stems from the diversity of sanitary surveillance activities, which requires knowledge of different areas (Law, Health, Engineering, etc.) and diverse practices, with notions of risk that may vary according to the strategy adopted[4].

In this sense, according to the structure of epidemiologist Naomar de Almeida Filho, cited by Leite and Navarro[4], it is possible to divide the various practices into three groups of strategies: Health Promotion, Risk or Damage Prevention, and Health Protection. Health Promotion is characterized by a broader strategy, not directed at a specific risk factor, and it presupposes educational actions. Health Prevention involves a strategy aimed at containing specific risk factors. Finally, Health Protection involves the control of non-specific (indeterminate) risks or risks that are not related to serial events; i.e. there is an epistemic uncertainty in this case.

With that in mind, we noticed that Health Prevention is based on specific risk factors in which a direct relationship between cause and undesired effect is sought or already established and, therefore, it is based on the probability of occurrence of the unwanted effect, often combined with the severity of the damage. Thus, we have the epidemiological approach to risk, also known as the classical concept of health risk. Therefore, what characterizes classic risk is the recurrence of events in series, which brings us an expectation of stability of the patterns of occurrence of the unwanted effects (damages). In this sense, epidemiological measures estimate risks from the identification of health conditioning factors and, consequently, of intervention objects by public health initiatives.

On the other hand, Health Protection aims to reinforce defenses in scenarios where the causes are not always known or where we are not able to isolate specific risks or, moreover, where serial events have not occurred. As stated above, in these situations there is an epistemic uncertainty, “derived from some level of ignorance or missing information about a system or the environment surrounding it”. Oberkampf et al., cited by Leite and

Navarro[4]. In short, there is epistemic uncertainty when one does not know or has little information about a problem to be solved or a decision to be made.

As mentioned by Leite and Navarro[4], in a health protection strategy - which concentrates many sanitary surveillance actions, particularly those focused on health services - the concept of classic risk is inapplicable because: 1) the causes of damage are not always fully known; 2) even when the causes are known, it is not possible to estimate the probability of occurrence of the unwanted effect; 3) there is an intrinsic and inseparable link between health protection practices and the context (i.e. the political, economic, and social conditions where the action takes place); 4) and, finally, the strategy addresses the points of control and not directly the sources of hazard (chemical, physical or biological agents or a set of conditions that present a source of risk) or the risk itself.

Control points result in risk monitors. These can be understood as signs or situations that allow the identification of potential risks in products, structures or processes, detected during sanitary inspection and that support evaluation and control actions. Risk monitors are warning signs, since they draw attention to the possibility of occurrence of unexpected damages or events, as explained by Costa[7]. Thus, isolated and often undervalued data, such as the absence of biological indicators in the process of sterilization of health products or the absence of preventive maintenance in diagnostic equipment, is now considered to have the significance of a risk or warning signal that may indicate the possibility of damages, requiring timely action by sanitary surveillance agents.

Silva and Lana[8] identified several meanings of risk among sanitary surveillance professionals. Through qualitative research carried out with some professionals of the federal, state and municipal levels, they identified that in the group of federal regulators (Anvisa) the predominant notion of risk is associated with statistics (probability), as some sort of byproduct of scientific research (at least in its evaluative stage). The notion of risk of local sanitary surveillance professionals is predominantly associated with non-compliance with a normative guideline, since it is the legislation that rules what is right. However, this apparently objective character is permeated by subjective elements, since the experience of the inspector is decisive in identifying the risks (or points of normative control). It is important to emphasize that this notion of risk implies two different ways of managing it: a bureaucratic approach (with absolute rule) and a technical-scientific approach (in which there is a greater interconnection between knowledge, experience and legislation).

According to researchers[4,9], the development of probability enabled the beginning of the risk quantification process. However, probability and risk are not synonyms for most disciplines: an event occurring with a higher frequency can be described as more probable, but not necessarily more risky, since it is fundamental to know how harmful the event will be. Risk assessment requires a value judgment and, therefore, is somewhat subjective. As stated by the authors, "risk is not a unit that is in nature to be measured, it is not independent from the observer and his interests. It is formulated and evaluated within a political, economic and social context, having a multifactor and multidimensional character".

In this sense, we understand that most of the risks posed by the technologies cannot be eliminated without also eliminating the benefits. Technology implies intrinsic risks, the possibility of new risks being added along its cycle and also incomplete scientific knowledge about the risks generated in many situations. Furthermore, it should be noted that the segmentation of the therapeutic process, specialization and the consequent plethora of professional assistants are increasing every day. On the one hand, this fragmentation of the work process favors and expedites care; on the other hand, it increases risks[7]. Therefore, the other dimensions of risk (other than probabilistic) are fundamental, among them acceptability, perception and confidence in the regulatory system.

As noted in the literature, risk perception studies show that risk assessments are not based only on statistical predictions. They also include knowledge, degree of novelty (and here lies much of the uncertainty) and familiarity, degree of personal control, potential for catastrophe, among others[8].

As regards regulation, it should be clarified that health regulations regulate procedures, products and equipment, i.e. health technologies, so as to produce maximum benefits at minimum risks, considering scientific, ethical, economic and social issues[4,9,10]. Thus, control actions are not necessarily related to hazards or sources of risks, but rather to environmental conditions, procedures, human resources, etc.[8] Therefore, the regulation actions of the Sanitary Surveillance of Health Services are generally focused on the control of risks, which makes it impossible (or at least extremely difficult) to find a cause-and-effect relationship[11]. We should bear in mind that regulation is the result of a value judgment, which will establish the limits of acceptability and control actions necessary to keep risks within acceptable limits. Therefore, this approach goes beyond the classic risk, because acceptability is mostly made up of non-quantifiable variables that take into consideration, besides technical issues, political, economic, social and cultural factors.

Therefore, in Health Protection there is the operational concept of potential risk, developed by Leite and Navarro[4]. In the words of the researchers, "the potential risk concerns the possibility of a health problem occurring, without necessarily describing the problem and its probability of occurrence. It is a concept that expresses the value judgment about potential exposure to a possible risk. It is as if it were the 'risk of risk'." It should be emphasized that the potential risk bears the notion of possibility of occurrence and not of probability (as is the case of classic risk); as the authors clarify, this difference is of paramount importance to the concept, since possibility is prior to probability, that is, something is only probable if it is possible. Therefore, from the epistemological point of view, the potential risk predates the classical risk.

For example, it is not possible to calculate the probability of a harmful event in the absence of a sanitary license or in the

absence of maintenance of a certain device, but given the current accumulated knowledge and in the proper questions about the risk control system, that may occur due to the absence of this type of control.

As Leite and Navarro propose[4], in the case of health protection strategies, the key element in risk management is the potential risk, which, even if it does not represent a defined cause-and-effect relationship, can be classified and quantified in levels of acceptability.

The risk acceptance threshold depends on its nature: origin, scope, severity, level of scientific determination, benefits and social factors. There is a tendency for individuals to underestimate/accept the risks they are aware of, while those risks whose scientific knowledge is still incomplete or which are known to have wide-ranging effects tend to be rejected or considered unacceptable[5].

As Silva and Lana point out[8], between the identification of the risk and the intervention there are processes that mix rationality (or objectivity) with subjectivity, acquired formal (or technical) knowledge with experience. Considering the idea of control points suggested by other researchers[4,7], Silva and Lana demonstrate that, although there is a ubiquitous presence of knowledge and experience in the practices of sanitary surveillance, it is the regulatory framework that tells what should be controlled or not.

We note that the complexity of the sanitary surveillance object - translated into the complexity of the health-disease process, concept of risk, interface with epidemiology, actions in the levels of promotion and protection - requires qualitative and quantitative approaches to be fully understood[11].

The qualitative approach results in risk assessments that express descriptive scales, using terms such as “low,” “medium,” or “high”[12]. In turn, the quantitative approach expresses numerical values, providing a more precise notion of the occurrence of an adverse event or the risk of a particular situation.

Finally, it should be emphasized that the qualitative risk assessment is considered to be faster and simpler when compared to a quantitative evaluation. Furthermore, it is used in initial assessments to identify cases that require further study, situations where the risk does not warrant the effort and time required for further analysis as well as in situations that do not provide enough information for us to quantify the variables established in a particular model[12].

With that in mind, we can say that there are several peculiarities regarding the sanitary risk in the field of Sanitary Surveillance of Health Services, however, there is no description of strategies or models applied to the analysis or handling of whistleblowing reports. It is therefore necessary to devise a particular strategy that can be adopted as an initial instrument to subsidize sanitary surveillance practices under the risk management paradigm, according to the elements that emerge from the bibliographic review.

Structuring assumptions

Control and social participation are important challenges within sanitary surveillance in terms of consolidating its model as a citizen health practice. In this sense, it is important to note that whistleblowing reports made by citizens and different entities are important drivers for health surveillance actions and practices.

Notwithstanding, not all local sanitary surveillance bodies managed to create a whistleblowing system to properly address various social demands and incorporate them to the management, planning and programming of health care[13].

On the other hand, sanitary surveillance activities are based on the notion of sanitary risk. In view of the absence of models or strategies based on a potential risk approach applied to the analysis or treatment of health service reports, we have put forward the assumptions of the model of potential risk, risk management, quality management in health services and social control to propose a prioritization strategy for the analysis and handling of potential risk reports.

Thus, from the point of view of the decision-making process based on risk management, and based on the theoretical framework of the potential risk, we arbitrate the adaptation of the problem prioritization matrix proposed by Kepner and Tregoe[14], called the SUT Matrix (Severity x Urgency x Tendency) in order to support decision-making processes for the analysis and handling of potential risk.

With regard to risk management and its intrinsic relationship with the quality management of health services, we considered the basic premises of health service quality evaluation proposed by Donabedian, based on the evaluation of patterns of structure, processes and results. According to that author, cited by Portela[15], while “structure” involves the organization and provision of the physical, human and financial resources required for health care, the “process” component refers to activities that occur in mediation between professionals and the assisted population. The “results”, in turn, relate to the effective changes promoted by the care based on the outcomes of those who are assisted.

Thus, the analysis and treatment of a whistleblowing report assumes that the “risk assessor” is familiar with the patterns of structure and processes required by the health standards, so that, before the report and in a preliminary manner, the risk can be assessed through risk monitors. On the other hand, when the whistleblowing involves possible adverse events, another approach is possible, since there are outcomes that should be considered in the analysis of rumors of adverse events, patient safety, or rumors of infectious events. These strategies are outside the scope of this article because they adopt a more classical epidemiological approach. Ultimately, the categories that are relevant and paramount to the potential risk model are structure and processes.

Another relevant category can be defined as criticality. Resolution RDC n. 50, of February 21, 2002[16], by the Anvisa Collegiate Board, associates criticality in health services with the notion of risk of infection based on a classification of areas. However, we consider

that the "infection" event is not the only possible outcome in health services, but also other non-infectious events or no objectively measurable and directly associated damage, as pointed out in the bibliographic review. Moreover, we suggest the extension of this scope not only to the environment where the care is provided, but also to the process itself, especially considering the technological density involved[17], the fragmentation of care processes and the degree of vulnerability of the patient[7], as well as other factors that would be responsible for the increase of uncertainty regarding possible harmful results. Thus, we propose the following classification:

- Critical structure and processes - Comprising both the physical environment and the processes and procedures with possible increased risk of infection transmission, with or without patients. It also includes physical environments, processes and procedures in which there is an inherent risk associated with greater technological density, such as in the assisted activities of radiation therapy, chemotherapy or analytical units in clinical laboratories, for example. Finally, it also includes those in which there is greater fragmentation of processes, causing a risk overlap for many processes and professionals, combined with greater vulnerability to the patient, as is the case of Intensive Care Units.

- Semi-critical structure and processes - Comprising both the physical environment and the processes and procedures with possible moderate to low risk for the development of infections related to health care, either by the execution of processes involving semi-critical articles, noninvasive therapy in non-critical patients, assistance to patients with infectious diseases of low transmissibility or non-infectious diseases. It also comprises physical environments, processes and procedures in which the presumed risk associated with the technological density is moderate to low. It also includes those in which there are fewer fragmented processes, with smaller risk overlap, combined with a lower relative degree of patient vulnerability, as is the case of care processes in a medical clinic.

- Non-critical structure and processes - Comprising both the physical environment and the processes and procedures when the possible risk for the development of care-related infections is minimal or non-existent, either by not carrying out care activities or because of the absence of processes involving critical and semi-critical articles. It includes the environments, processes or procedures in which there is no direct assistance to the patient, associated with low exposure to occupational risks. It also includes physical environments, processes and procedures in which the risk associated with technological density is low or non-existent, due to the predominance of light technologies in the assistance.

Another relevant factor in whistleblowing management is the "time" (or "tendency") category, that is, whether there is the need for immediate intervention or not.

It is these categories, together with essential elements we found in our literature review (and condensed below), that enabled the development of the proposed strategy and its flowchart. Thus, in order to understand the rationale of the "Priority Strategy for Whistleblowing" presented below, it is worth recapping some points that we deem essential in the literature.

Context for the construction of a strategy of prioritization of health service whistleblowing reports based on potential risk

According to the literature, despite its wide variety of meanings, risk is usually associated with the idea of predicting an unwanted future event. In addition, potential risk is associated with strategies that address points of control (or warning signs), scenarios where we are unable to isolate specific causes and situations nor estimate the probability of occurrence of the unwanted effect (or that serial events have not occurred).

It should be noted that potential risk bears the notion of possibility of occurrence rather than probability (as occurs in classical risk); the possibility thus comes before the probability. Moreover, in health protection strategies, the key element in risk management is the potential risk, which, even if it does not represent a clear-cut cause-and-effect relationship, can be classified and quantified in levels of acceptability.

Technologies have intrinsic risks. If on the one hand the fragmentation of work processes favors and accelerates care, on the other, it increases the risk associated with health care.

Therefore, through a qualitative strategy, we can think that the existence of a structural or process problem in a critical environment (where there is a higher inherent risk due, for example, to the density of technology and more fragmented processes, combined with greater patient vulnerability) can result in immediate damage of greater severity. That is, this problem can be considered serious.

In the case, for example, of a generally described crack in the wall, we may not consider that it could result in immediate damage, but we can consider that there is a tendency that the problem will grow (and so will its possibility of damage) if there is no intervention.

Thus, the first variable to be considered is *severity*. We define severity as the "possibility of immediate damage to the person" and "criticality of the structure/process".

So the first questions to ask are:

- Is it a structure or process problem related to a critical activity/environment/procedure and that can result in immediate damage?

- Is it a structure or process problem related to semi-critical activity/environment/procedure and that can result in immediate damage?

- Is it a structure or process problem related to a non-critical activity/environment/procedure but that can result in immediate damage?

However, as stated above, most problems tend to grow. So in addition to severity, we can think of the *tendency* of the problem.

The combination of these two dimensions gives us insight into their treatment *priority*.

We have defined three levels of *tendency*:

- High tendency: a situation that tends to worsen rapidly.
- Medium tendency: a situation that tends to stay the same or worsen in the medium term.
- Low tendency: a situation that does not tend to worsen or even tends to improve over time.

A remark is necessary here: we clarify that, due to methodological rigor, we use the term degree of priority instead of degree of risk, because our object (the potential risk) is not subject to direct cause-and-effect relationships and requires a strategy, which, despite the attempt to establish various objective criteria, still results to a certain extent from a value judgment that will establish the limits of acceptability and control actions necessary to keep risks within acceptable limits based on what was pointed out in the whistleblowing report.

Therefore, according to this stratification, we can establish the following priorities (Figure):

- Priority 1 (P1): 1) High severity problems with tendency result in a high priority perception.
- Priority 2 (P2): 2) High severity problems with medium or low tendency; or 3) Problems of medium severity with high tendency result in a priority perception.
- Priority 3 (P3): 4) Low severity problems with high tendency; or 5) Medium-severity problems, with medium or low tendency, resulting in a relative priority perception.
- Priority 4 (P4): 6) Low severity problems with medium or low tendency; or 7) Problems without severity with a medium or low tendency result in low priority.
- Priority 5 (P5): 8) Problems with no possibility of damage result in a very low priority perception.

We emphasize that a problem without severity will never have a high tendency, otherwise it would be a problem with possibility of immediate damage. Additionally, according to this rationale, a problem "without severity" cannot be understood as a problem without possibility of damage.

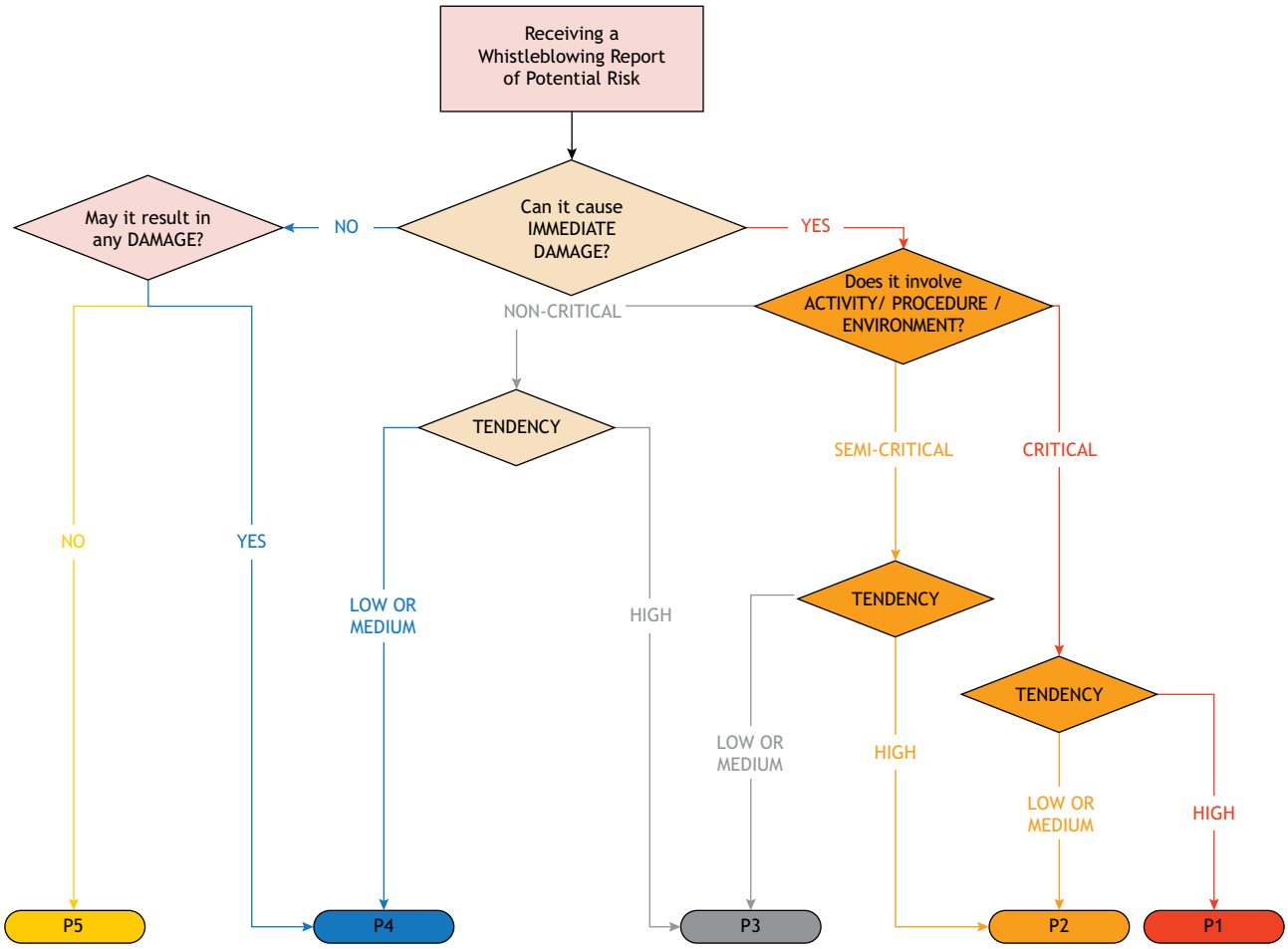

Figure. Flowchart for a strategy of prioritization of potential risk whistleblowing reports.

CONCLUSIONS

The incorporation of the risk management paradigm into the Sanitary Surveillance of Health Services remains an important challenge, especially when Sanitary Surveillance has to deal with situations perceived as having potential risk. Although there is a relatively recent discussion about the model of potential risk analysis as an operative concept for the field of Sanitary Surveillance of Health Services, there is no description of strategies or models applied to the analysis or treatment of whistleblowing reports, although this is a daily practice of Sanitary Surveillance bodies.

Thus, the presented strategy is an initial instrument for the systematization of the analysis and handling of potential risk reports in health services, which should be discussed and adapted to the reality and context of the Sanitary Surveillance bodies, but which appears as an alternative in the absence of other instruments for this purpose.

For the operationalization of the risk management paradigm with regard to sanitary surveillance practices focused on potential risks, we need more studies, discussion and research to think about the limits and possibilities of this theoretical model combined with the practices of sanitary surveillance and other approaches to risk management.

REFERENCES

1. Costa EA, organizador. Vigilância sanitária: temas para debate. Salvador: EDUFBA; 2009.
2. Lucchesi G. Vigilância sanitária: o elo perdido. Divulg Saúde Debate. 1992;(7):48-52.
3. Brasil. Lei Nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. Diário Oficial União. 27 jan 1999.
4. Leite HJD, Navarro MVT. Risco potencial: um conceito de risco operativo para vigilância sanitária. In: Costa EA, org. Vigilância sanitária: temas para debate. Salvador: EDUFBA; 2009. p. 61-82.
5. Barbosa AO, Costa EA. Os sentidos de segurança sanitária no discurso da Agência Nacional de Vigilância Sanitária. Cien Saúde Coletiva. 2010;15(suppl 3):3361-70. https://doi.org/10.1590/S1413-81232010000900011
6. Freitas FP, Oliveira BMS. Irregularidades sanitárias como marcador de risco à saúde: um desafio para a vigilância sanitária. Vigil Sanit Debate. 2013;1(1):43-51. https://doi.org/10.3395/vd.v1i1.4.
7. Costa EAM. Vigilância sanitária em serviços de saúde: os desafios da prática. Vigil Sanit Debate. 2014;2(2):27-33. https://doi.org/10.3395/vd.v2i2.148
8. Silva AVFG, Lana FCF. Significando o risco sanitário: modos de atuação sobre o risco na vigilância sanitária. Vigil Sanit Debate. 2014;2(2):17-26. https://doi.org/10.3395/vd.v2i2.145.
9. Navarro MVT, organizador. Risco, radiodiagnóstico e vigilância sanitária. Salvador: EDUFBA; 2009.
10. Navarro MVT, Costa EA, Drexler GG. Controle de riscos em radiodiagnóstico: uma abordagem de vigilância sanitária. Cienc Saúde Coletiva. 2010;15(suppl 3):3477-86. https:/doi.org/10.1590/S1413-81232010000900022
11. Lucena RCB. Os caminhos metodológicos para o estudo da vigilância sanitária. Rev Bras Prom Saúde. 2013;26(1):145-150. https://doi.org/10.5020/18061230.2013.p146
12. Santos D V., Todeschini B, Rocha CMBM, Corbellini LG. A análise de risco como ferramenta estratégica para o serviço veterinário oficial brasileiro: dificuldades e desafios. Pesq Vet Bras. 2014;34(6):542-554. https://doi.org/10.1590/S0100-736X2014000600008.
13. Bernadete M, Eduardo P. Vigilância sanitária para gestores municipais de serviços de saúde. São Paulo: Fundação Peirópolisa; 1998[acesso 6 ago 2017]. (Série Saúde & Cidadania). Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/saude_cidadania_volume08.pdf
14. Kepner CH, Tregoe BB. The new rational manager: an updated edition for the new world. Princeton: McGraw-Hill; 2013.
15. Portela MC. Avaliação da qualidade em saúde. In: Rozenfeld S, organizador. Fundamentos da vigilância sanitária. Rio de Janeiro: Editora Fiocruz; 2000.
16. Agência Nacional de Vigilância Sanitária - Anvisa. RDC N° 50, de 21 de fevereiro de 2002. Dispõe sobre o Regulamento Técnico para planejamento, programação, elaboração e avaliação de projetos físicos de estabelecimentos assistenciais de saúde. Diário Oficial União. 18 nov 2002.
17. Merhy EE. Em busca do tempo perdido: a micropolítica do trabalho vivo em saúde. In: Merhy EE, Onoko R, organizadores. Agir em saúde: um desafio para o público. São Paulo: Hucitec; 1977. p. 71-112.

Acknowledgement

We thank the Regulation and Sanitary Control Management of Health Services of the Brazilian Sanitary Surveillance Agency for promoting the discussions that led to the development of the proposed strategy.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.