

Potential risk assessment: from theory to practice in Health Surveillance

Avaliação do risco potencial: da teoria à prática em Vigilância Sanitária

ABSTRACT

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Introduction: The great challenge of health control is to evaluate the potential risk of its multiple objects of action, using the results to select the best strategies, a task difficult to be operationalized in the daily routine of the Sanitary Surveillance (Visa). **Objective:** To present the operationalization of the Model of Potential Risk Assessment (MARP) in health services in the state of Santa Catarina (SC), in order to support reflections about the applicability of this method. **Method:** Descriptive study of holistic multiple cases. The unit of analysis was the sanitary control of health services carried out by the Visa of SC, in Greater Florianópolis, and 15 (42.9%) of the 35 hospitals in this region. The risk assessment strategy was MARP with application of Objective Inspection Scripts, in the Surgical Center (SC), Sterilized Material Center (SMC) and Intensive Care Unit (ICU), in the years 2017 to 2019. **Results:** The ICU presented the highest percentages of acceptable risk and the lowest percentages of unacceptable risk, while the CME presented the lowest acceptable risk percentages and the highest percentages of unacceptable risk. The percentages of acceptable potential risk are higher in the CC of large hospitals, in the ICU of medium-sized hospitals and absent in the CME and CC of small hospitals. **Conclusions:** MARP favors the management of risks in Visa and the direction of its health control actions. It has limitations, when requiring an information system and needs understanding of the results of the data, considering that risk and benefit are challenging concepts and should be analyzed in a defined context.

KEYWORDS: Health Surveillance; Risk; Regulation; Health Services

RESUMO

Introdução: O grande desafio do controle sanitário é avaliar o risco potencial de seus múltiplos objetos de ação, utilizando os resultados para selecionar as melhores estratégias, tarefa difícil de ser operacionalizada no cotidiano da Vigilância Sanitária (Visa). **Objetivo:** Apresentar a operacionalização do Modelo de Avaliação de Riscos Potenciais (MARP) em serviços de saúde do estado de Santa Catarina, de modo a subsidiar reflexões acerca da aplicabilidade desse método. **Método:** Estudo descritivo de casos múltiplos holísticos. A unidade de análise foi o controle sanitário de serviços de saúde realizado pela Visa de Santa Catarina, na Grande Florianópolis, tendo sido estudados 15 (42,9%) dos 35 hospitais dessa região. A estratégia de avaliação de risco foi o MARP com aplicação de Roteiros Objetivos de Inspeção, nos Centros Cirúrgicos (CC), nas Centrais de Material Esterelizado (CME) e nas Unidades de Terapia Intensiva (UTI), nos anos 2017 a 2019. **Resultados:** As UTI apresentaram os maiores percentuais de risco aceitável e os menores de risco não aceitável, enquanto as CME apresentaram os menores percentuais de risco aceitável e os maiores de risco não aceitável. Os percentuais de risco potencial aceitável são maiores nos CC dos hospitais de grande porte, nas UTI dos hospitais de médio porte e ausente nas CME e nos CC dos hospitais de pequeno porte. **Conclusões:** O MARP favorece o gerenciamento dos riscos em Visa e o direcionamento de suas ações de controle sanitário. Possui limitações, ao necessitar de um sistema de informação e requer compreensão dos resultados dos dados, tendo em vista que risco e benefício são conceitos desafiadores e devem ser analisados num contexto definido.

PALAVRAS-CHAVE: Vigilância Sanitária; Risco; Regulação; Serviços de Saúde

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INTRODUCTION

The Health Surveillance (Visa) is a constituent part of the Unified Health System (SUS), integrates public health as a field of theoretical and practical interest, and has the constitutional responsibility to prevent and control risks related to products, processes, and services of interest to human health¹.

Risk benchmarks are used in several areas of knowledge and in health they have been consolidated as “the probability of occurrence of an adverse event and its severity, used as a measure of impact or associated with differences in morbidity or mortality between groups, with and without a certain attribute, constituting the epidemiological or classic risk”², acquiring, then, a quantitative perception, based on the associability of events to infer susceptibility probabilities according to the degree of exposure to certain agents^{3,4,5}.

Regardless of the polysemy of the term, risk is a central element in Visa’s actions and must be the inductor of rational decision-making. However, for Visa, in addition to the concept of epidemiological risk supported by probabilistic scientific evidence, a concept that goes beyond the cause-effect relationship, so typical and evident of the classic risk concept, is necessary for an understanding of risk that can happen even in the absence of this causal link^{3,6}.

We are talking about the potential risk, as the possibility of damage, since Visa, in the practice of sanitary control of its multiple, distinct, and growing objects of action (water and food, waste, cosmetics, germicides, medicines, blood, health services, radiology, schools, street food, prisons, cemeteries, etc.), in the vast majority of situations, cannot establish the association of common cause and effect of studies and epidemiological surveillance^{3,6}.

It is known that Visa’s objects of action have particular characteristics: they are of interest to human health; produce benefits and have intrinsic risks. Thus, if the risk *versus* benefit ratio is favorable to the benefit, it is essential to understand the acceptability of the risk in certain contexts of sanitary control, a process that not only depends on technical-scientific evaluations, but also on the perception of risk associated with cultural aspects and the use of the benefit^{3,5,6}.

Benefit is a concept under construction in the health area and has been used by regulatory bodies in the areas of control of medicines, food, and medical devices. It can be understood as the opposite of risk and symmetrically understood as the condition or context of exposure to a certain attribute of a technology, which has a certain probability of causing a favorable situation, with a certain magnitude. These are the “favorable effects” for a target population associated with a process, service, or product^{5,7,8,9,10}.

Thus, while the potential risk can be understood as the possibility of an unfavorable effect occurring, without necessarily describing the effect and its probability, the potential

benefit can be defined as the possibility of a favorable effect occurring, without necessarily describing the effect and its probability^{7,8,9,10}.

The concepts and risk and benefit assessment are challenging when applying these in the practice of sanitary control carried out by Visas, being central to regulatory decision-making, contributing to effective, transparent, and reliable sanitary actions among the sectors involved^{3,4,9}.

These concepts support the assessment of the daily practice of Visa control, such as how to determine the risk of a surgical patient undergoing a procedure with instruments without sterilization control. It also helps in classifying the risk related to the absence of standard care protocols, among other countless everyday and emblematic situations for Visa professionals who, often, driven by common sense rationalities, carry out ineffective interventions, with high economic and environmental costs, and that in no way contribute to the control of risks and benefits in health services¹¹.

Additionally, for the sanitary control of health services, Visa uses inspection scripts, which constitute evaluation instruments with binary responses and that classify the situations identified in the services as “conforming or non-conforming”, “yes or no”, “high, medium, or low risk”, with a considerable amount of subjectivity, both in relation to the service, product, or process to be evaluated, as well as the varied interpretations of the regulatory frameworks used for this purpose^{3,11}.

In this sense, the great challenge of sanitary control is to evaluate the risk and guarantee the benefit of its multiple objects of action without underestimating them and without overvaluing them, as well as using the data from the risk and benefit assessment to implement their management, selecting the best policies and strategies for risk control, a difficult task to be operationalized in Visa’s daily life.

Potential Risk Assessment Model and Inspection Objective Roadmap (PRAM & IOR)

To operationalize the concept of potential risk (PR), Navarro¹² developed the Potential Risk Assessment Model (PRAM), through the classification of risk control indicators, which are items taken from the sanitary regulations and which make up an inspection instrument, it is possible to measure the potential risk of the service evaluated.

As a way of making the assessment as realistic as possible, PRAM quantifies the indicators on the following scale: 0 (the worst situation, in which there is a total absence or non-compliance with the rules); 1: poor (less than partially meeting the norm); 2: reasonable (meets the standard, but not fully); 3: good (meets what the standard determines); 4: excellent (meets more than the standard determines); 5: excellent (presents requirements for excellence in quality of care); NE: not evaluated¹².



The indicators used in the inspection instrument are classified as critical (I_c) and non-critical (I_{NC}), depending on the severity and possible associated risk. The critical ones can take the system to the maximum potential risk if they are assessed as the zero situation. The non-critical ones influence the risk value, but do not determine the maximum potential risk, except when the entire set of these is evaluated in the zero situation¹².

Thus, PR was defined as:

$$R_p = \sqrt{\sqrt[N]{\prod_{i=1}^N I_{c_i}} \times \frac{\sum_{j=1}^M I_{NC_j}}{M}} \quad (1)$$

The first term of the square root being the geometric mean of the N critical indicators (I_{c_i}) and the second term the arithmetic mean of the M non-critical indicators (I_{NC_j}).

However, the classification of indicators between zero and five continued to bring a lot of subjectivity to PRAM. Aiming to improve the method by incorporating transparency and objectivity, a new inspection technology called Inspection Objective Roadmap (IOR) was developed, which describes verification items of the evaluation units, providing greater detail on the possible situations encountered, as exemplified in Figure 1. In this way, IOR allows the reproducibility of the evaluation of a service independent of the technician that makes use of this instrument⁶.

IOR can be built for the most diverse areas of Visa and in the state of Santa Catarina (SC) it has already been prepared for the following services: Intensive Care Unit (ICU - neonatal, pediatric and adult), Surgical Center (SC), urgency and emergency, endoscopy (types I, II, and III), Hospitalization Unit, Laboratory Collection Station, pharmacies (hospital, manipulation and without manipulation), laboratories (microbiology, clinical, pathological and analytical anatomy), patient safety, Material and Sterilization Center (MSC - types I and II), dialysis, nutrition and dietetics, medical radiology, nuclear medicine, and radiotherapy services.

The assessment results classify the inspected units into three risk levels: acceptable, tolerable, and unacceptable; depending on the potential risk value calculated in each inspection, according to the Table.

The classification of the PR value signals possible decision making. If the PR is high ($PR > 0.360$), the tendency is that there will be a ban or suspension of activities in the service. When the result is tolerable, the service can receive notification for correction of non-conformities within a defined period, and if the risk is acceptable, the sanitary license will certainly be released.

This study aimed to present the operationalization of PRAM in health services in the state of Santa Catarina, in order to support reflections on the applicability of this method in the sanitary control carried out by Visa.

METHOD

It is a descriptive study of multiple holistic cases. A case study is an empirical investigation that analyzes a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly defined. It includes both single case (one unit under evaluation) and multiple case studies (several units under evaluation). They are classified as holistic if they have only one unit of analysis¹³.

The unit of analysis of this study is the sanitary control of health services carried out by SC's State Visa in health services of that state, called "cases" in this methodology.

In 2017, SC's Visa started using PRAM & IOR in hospitals in Greater Florianópolis, which comprises a region with 22 municipalities. Among the 35 hospitals located in this region, 15 (42.9%) participated in the study, which represented the "cases" of this study, as they had an ICU, SC, and MSC.

The risk assessment strategy adopted for these health services was the PRAM with application of the IOR, in which the risk control indicators present in health legislation are considered, classified as critical or non-critical and described in six possible situations (0 to 5).

For each service/unit of the hospital organization studied, an IOR was prepared, used as a legal instrument for inspection, and the health standards considered the gold standard for evaluating the PRAM.

Each IOR was made available in pdf format, and, after application, the data were entered into the State Risk and Potential Benefit Information System (SIERBP), implemented by the state of SC, through Normative Resolution No. 3, of September 27, 2019¹⁴. This system aims to obtain computerized records about health services and health interests, as well as manage and standardize health inspections and self-inspections using PRAM methodology and the IOR assessment instrument.

In this study, we are presenting data from the sanitary control of the SC, MSC, and ICU units, evaluated according to their IOR, specific and applied in the hospitals studied by SC's Visa professionals, in a timely manner in the years 2017, 2018, and 2019.

RESULTS AND DISCUSSION

We present below the results of the application of IOR according to PRAM, of the SC, MSC, and ICU units of the hospitals inspected by SC's Visa, in the period between 2017 and 2019.

Figure 2 presents the assessment of potential risk classified in this methodology as acceptable, tolerable, and unacceptable for hospitals located in Greater Florianópolis.

It can be seen in Figure 2 that the three evaluated units have the three levels of risk predicted by PRAM, with the ICUs having



Roteiro Objetivo de Inspeção: UTI Adulto								
<p>Unidade de Saúde: Identificação do serviço: Contato:</p>		<p>Data: Avaliador:</p>		<p>Documento: 1.1 Versão: 1.4 Data: 28.05.2018 Marco Regulatório</p>				
Indicador	Critica	Aval	0	1	2	3	4	5
Responsável Técnico (RT)	NC	Ausência de RT.	Possui RT médico, mas sem título de especialista em Medicina Intensiva de acordo com o perfil da Unidade.	Possui RT médico, mas não está formalmente designado pela Direção da Instituição e/ou não dispõe de substituto.	UTI possui responsável técnico, médico com título de especialista, conforme estabelecidos pelos respectivos conselhos de classe.	RT e substitutos com títulos de especialista em Terapia Intensiva ou outra relacionada ao atendimento ao paciente grave de acordo com o perfil da Unidade.	RT atua exclusivamente em um único estabelecimento.	Art. 13 da RDC nº 137/2017
Coordenadores	NC	Ausência de Coordenadores de Enfermagem e Fisioterapia no setor.	Possui coordenador de enfermagem e fisioterapia, mas sem título de especialista.	Possui coordenadores de enfermagem e de fisioterapia, mas não estão formalmente designados pela Direção da Instituição e/ou não dispõem de substitutos.	Possui coordenadores de enfermagem e de fisioterapia e substitutos com título de especialista, conforme estabelecidos pelos respectivos conselhos de classe.	Coordenadores e substitutos com título de especialista em Terapia Intensiva ou outro relacionado ao atendimento ao paciente grave, de acordo com o perfil da Unidade.	Coordenadores atuam exclusivamente em um único estabelecimento.	Art. 13 da RDC nº 137/2017
Dimensionamento da Equipe	C	Não há profissional médico em, pelo menos, algum dos períodos.	Equipe multiprofissional do setor está subdimensionada, não dispondo de um ou mais dos profissionais ou não perfazendo o horário estabelecido em legislação.	Equipe multiprofissional da UTI está devidamente dimensionada, exceto por não dispor de médico diarista e/ou médico plantonista concomitante.	Equipe multiprofissional da UTI conta com: médico diarista/especialista (1/10 leitos M/T), médico plantonista, especialista (1/10 leitos/turno), enfermeiro assistencial (1/10 leitos/turno), fisioterapeuta (1/10 leitos/18 h de atuação), técnico de enfermagem (1/2 leitos/turno), técnico adm. para serviço apoio (1/turno), auxiliar administrativo exclusivo da unidade; auxiliar de higiene exclusivo para o setor.	Existe plano de contingência para substituição de pessoal em situações de necessidade do serviço.	Art. 14 da RDC nº 07/2010 e Art. 1º da RDC nº 26/2012	
Treinamento de Pessoal	NC	Não realiza.	Existem poucos registros das capacitações realizadas, as mesmas não são realizadas de forma permanente.	Existem registros das capacitações realizadas de forma permanente com informações incompletas.	Existem registros de capacitações realizadas de forma permanente contendo data, horário, carga horária, conteúdo ministrado, nome e formação do instrutor e dos profissionais envolvidos.	Existe planejamento das capacitações e há registro de relatórios de avaliação com percentual de treinados.	A capacitação dos profissionais inclui incentivo (financeiro ou não) da organização para participação em eventos científicos da área.	Arts. 32 e 33 da RDC nº 63/2011 e Art. 17 da RDC nº 07/2010
Padronização de Normas e Rotinas dos Procedimentos Assistenciais	NC	Não dispõe de normas, procedimentos e rotinas técnicas.	Normas, procedimentos e rotinas técnicas estão em elaboração ou diferem da prática realizada ou não estão disponíveis para a equipe.	Dispõe de normas, procedimentos e rotinas técnicas escritas de todos os processos de trabalho em local de fácil acesso a toda equipe, porém não estão atualizadas e/ou sem aprovação.	Dispõe de normas, procedimentos e rotinas técnicas escritas de todos os processos de trabalho, atualizadas e aprovadas, assinadas pelo RT e pelos coordenadores de enfermagem e de fisioterapia, em local de fácil acesso a toda equipe.	Normas, procedimentos e rotinas técnicas são revisados sistematicamente a cada introdução de nova tecnologia no setor com registro de divulgação e treinamento dos profissionais.	Existe auditoria interna para verificação do cumprimento das normas, procedimentos e rotinas técnicas e medidas corretivas são adotadas e registradas.	Arts. 8º e 9º da RDC nº 07/2010, Arts. 7º Inciso II alínea "d", 23 Inciso XVIII e 51 da RDC nº 63/2011

Source: Elaborated by the authors, 2020.
 ICU: Intensive Care Unit; RT: responsible technician; NC: not critical; C: Critical; RDC: Resolution of the Collegiate Board of Directors.

Figure 1. Intensive Care Unit Inspection Objective Roadmap.



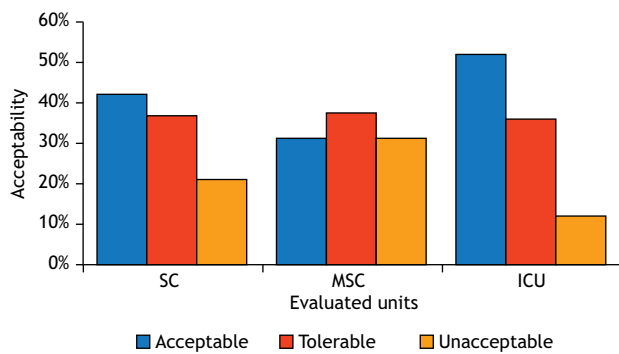
the highest percentages of acceptable risk (52%), followed by the SC (42%), and finally the MSC (31%). The tolerable risk rating of these units was 36% in the ICU, 37% in the SC, and 37% in the MSC. The risk classified as unacceptable was higher in MSC (31%), followed by SC (21%) and ICU (12%).

These data reveal that, of the three units evaluated in the hospitals in Greater Florianópolis, ICUs have the highest percentages of acceptable risk and the lowest percentages of unacceptable

Chart. Potential risk (PR) rating.

Classification of PR values	
Acceptable	$PR \leq 0.049$
Tolerable	$0.049 < PR \leq 0.360$
Unacceptable	$PR > 0.360$

Source: Elaborated by the authors, 2020.



Source: Elaborated by the authors, 2020.

SC: Surgical Center; MSC: Material and Sterilization Center; ICU: Intensive Care Unit.

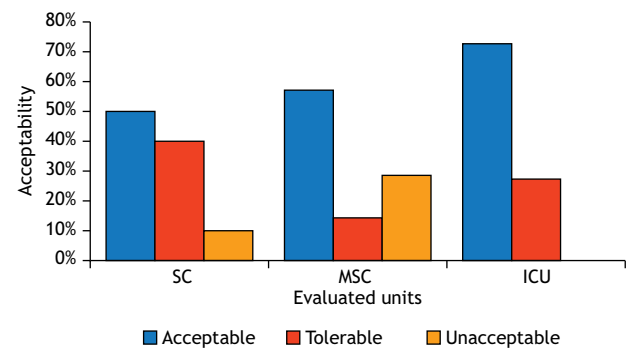
Figure 2. Risk classification according to the Potential Risk Assessment Model (PRAM) applied in hospitals located in Greater Florianópolis from 2017 to 2019.

risk, and MSCs have the highest percentages of unacceptable risk and the lowest percentages of acceptable risk.

Figures 3, 4, and 5 present the risk classification of hospitals in Greater Florianópolis according to the number of beds, using the classification adopted by De Negri¹⁵, in which small hospitals are those with up to 50 beds, medium-sized hospitals with 51 to 150 beds, and large hospitals are those with more than 150 beds.

In Figure 3, it can be seen that the SCs of large hospitals in Florianópolis have the highest percentages of acceptable risk (75%), followed by ICUs (45%) and MSCs (25%). The tolerable risk in the three units evaluated was identified in 75% of MSCs, 33% in ICUs, and absent in SCs. The unacceptable risk is higher in the SC (25%), followed by the ICU (22%) and no percentage of this risk in the MSC of these hospitals.

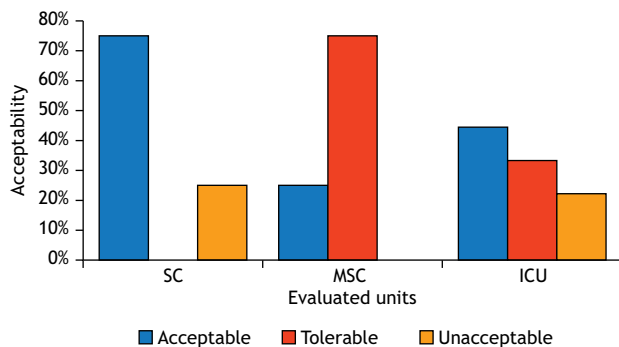
These data indicate that the potential acceptable risk is higher in large hospitals' SCs, but these units also have the highest



Source: Elaborated by the authors, 2020.

SC: Surgical Center; MSC: Material and Sterilization Center; ICU: Intensive Care Unit.

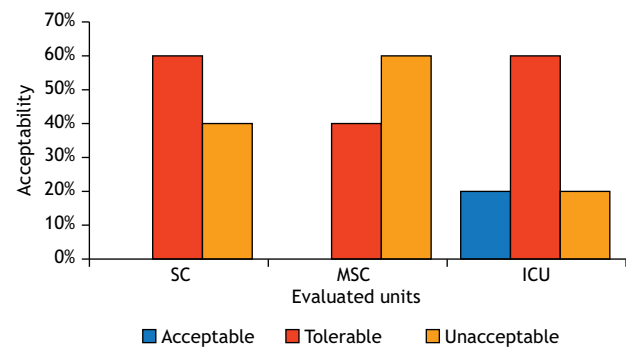
Figure 4. Risk classification according to the Potential Risk Assessment Model (PRAM) in medium hospitals located in Greater Florianópolis from 2017 to 2019.



Source: Elaborated by the authors, 2020.

SC: Surgical Center; MSC: Material and Sterilization Center; ICU: Intensive Care Unit.

Figure 3. Risk classification according to the Potential Risk Assessment Model (PRAM) in large hospitals located in Greater Florianópolis from 2017 to 2019.



Source: Elaborated by the authors, 2020.

SC: Surgical Center; MSC: Material and Sterilization Center; ICU: Intensive Care Unit.

Figure 5. Risk classification according to the Potential Risk Assessment Model (PRAM) in small hospitals located in Greater Florianópolis from 2017 to 2019.



percentages of unacceptable risk. The MSCs have the lowest percentages of acceptable risk and no unacceptable risk, and large hospitals' ICUs have a potential risk in the three classifications, with the acceptable being 45%.

In medium-sized hospitals, the acceptable potential risk has a more uniform distribution, with percentages of 73% in ICUs, 57% in MSCs, and 50% in SCs. The tolerable risk is higher in SC (40%), followed by ICU (27%) and MSC (14%). The unacceptable risk is absent in ICUs, but present in MSCs (29%) and CCs (10%).

The data from the risk assessment of medium-sized hospitals differ from the data identified in large hospitals, as they reveal that the ICUs are the most acceptable risk units (73%), while in large hospitals they are the SCs. ICUs are also the units where unacceptable risk is absent.

Figure 5 shows a predominance of potential risk classified as tolerable and unacceptable in small hospitals in Greater Florianópolis. The tolerable risk percentages are 60% in the SC and ICU and 40% in the MSC and the unacceptable risk is 60% in the MSC, 40% in the SC, and 20% in the ICU. Acceptable risk is absent in the SC and MSCs of these hospitals.

The results of the risk assessment, according to the MARP, arising from the absence or failure to comply with the health standards issued by the Brazilian National Health Surveillance Agency (Anvisa) and applied in the hospitals of this study, revealed that this method is feasible and effective in identifying potential risks of these services¹².

The SC, ICU, and CME units for this evaluation are sectors considered of high specificity of care, pillars for the quality of hospital care and essential for patient safety and prevention of adverse events related to surgeries, invasive procedures, and the reuse and reprocessing of medical devices¹⁶.

It was identified that, in hospitals in Greater Florianópolis, the ICUs had the highest percentages of acceptable risk and the lowest percentages of unacceptable risk, while, conversely, the MSCs showed the lowest percentages of acceptable risk and the highest percentages of unacceptable risk. The SC presented 42% of acceptable risk and 21% of unacceptable risk, indicating, in this study, that the ICUs stand out as the units with the best potential risk assessment performance, followed by the SC and the MSC.

This assessment constitutes the first quantitative study of potential risk in hospital services in Brazil and, despite the incipient use of this methodology applied to the sanitary control of Visa's health services, these data point to the need to improve the organostructural and care processes of the three evaluated units, especially for MSC.

The acceptable risk percentage of 52% for critical care units, which serve mostly critically ill patients and who require invasive procedures and massive use of drugs, including antimicrobials, seems to us to be a lower percentage than desired, even considering that at this time there are no acceptable risk

percentages for critical units that can serve as a benchmark or standard indicator for better analysis purposes.

The same rationality for the SCs that constitute highly complex units due to the risk procedures performed and for the MSC sectors responsible for the cleaning, disinfection, sterilization, and quality control processes of medical products used in most care procedures and that presented, in this study, low percentages of acceptable risk, such as 42% and 31%, respectively.

In this sense, it is important to ratify that the control of care risks is intrinsically related to the monitoring of quality and safety in health and requires the implementation of highly reliable practices in the provision of health care, a fundamental strategy for harm reduction¹⁷.

Additionally, the quality and safety of hospital services are a technical and social imperative that must remain at the forefront of health care, in order to optimize the desirable effects (benefits) and minimize the undesirable ones (damage), in order to correspond with the increasing levels of user demand for safe and risk-controlled health services, which demands from the State, particularly Visa, effectiveness of actions, relevant decision-making, and reorientation of their health control strategies^{18,7,10}.

The stratified analysis of the potential risk of the hospitals studied, according to the number of beds *versus* evaluated units, provides a different picture from that shown in Figure 2.

Acceptable risk percentages are higher in SC (75%) of large hospitals, higher in ICU (73%) of medium-sized hospitals, and absent in MSC and SC of small hospitals. These data may reflect different situations, such as greater investments in human and technological resources in hospitals with great care demands (large and medium-sized). They may also reflect greater health control on the part of Visa, since they are organizations considered to be more complex and with greater social visibility.

In medium-sized hospitals, the highest percentages of acceptable risk in this study predominate, with rates of 73% in the ICU, 57% in the MSC, and 50% in the SC. Percentages of tolerable and unacceptable risk are the most prevalent in small hospitals, in all three units evaluated, confirming previous data and highlighting the need to reinforce sanitary control in these services.

The applicability of PRAM by SC's Visa in hospitals in Greater Florianópolis made it possible to identify potential risks in highly relevant units, providing the health agency with instruments for action based on indicators according to current health standards, with the results indicating the agreement with authors who advocate the use of a quantitative methodological framework of risk and benefit, in the evaluation of complex structures, such as the hospital services studied here⁵.

The quantitative and parameterized results of this method allowed the classification of the acceptability of potential risks, both for the evaluated units (ICU, MSC, and SC) and for hospital size. With that, Visa identified the main problems and where



they are, in order to direct its actions to the units and hospitals with the greatest potential risk.

These results also allow the monitoring of the temporal evolution of the potential risks of the services, providing the construction of their historicities, indicating trends of compliance or non-compliance. Additionally, it supports Visa in the effective taking of risk prevention and control actions, to the extent that, when analyzing a historical trend, it can intervene in the service, before the risk classification change, from acceptable to tolerable or even from acceptable to unacceptable.

It is important to emphasize the reproducibility and transparency that the method adds to the health inspection process, since it objectively identifies the situation of each risk control indicator, making it possible for the regulated sector to know unequivocally what the identified situation is, as well as significantly reduces the personality of the evaluation process, preventing different evaluators from indicating different situations encountered.

In addition to being useful in the most diverse practices of Visa, ranging from regulation to inspection, PRAM & IOR can also be a

tool to be used in the contracting process of health departments, in order to contribute to improving the quality and safety of the services offered by SUS, such as the Santa Catarina hospital policy of 2019, which included PRAM & IOR as one of the criteria for contracting¹⁴.

CONCLUSIONS

This study is a pioneer in presenting sanitary inspection data in hospital services, using a methodology centered on the potential risk, thus starting a different path from that hitherto followed by Brazilian Visa services and a new paradigm of sanitary control.

The assessment of risk and benefit in hospital services using a quantitative model favors the management of risks in health surveillance and the direction of its actions of health control. However, it has limitations, as it requires an information system and presents operational difficulties for some services. Another consideration concerns the understanding of data results, given that risk and benefit are challenging concepts and must be analyzed in a defined context.

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Author's Contributions

Navarro MVT, Costa EAM, Freitas VLMS, Duarte LGC - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Freitas L, Kindermann C - Acquisition, analysis, data interpretation, and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.



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