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Main irregularities in establishments subject to sanitary control

Principais irregularidades em estabelecimentos sujeitos a controle sanitário

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ABSTRACT

Introduction: Sanitary inspection verifies compliance with technical standards and regulations for safety and quality. The Health Surveillance of Minas Gerais has a notification procedure for sanitary risk situations that allows the systematic collection and analysis of data related to health inspections. These data are used to identify the sanitary hazard in the territory and the consequent definition of actions. **Objective:** To determine the irregularities most frequently encountered during health inspections carried out in Minas Gerais. **Method:** Cross-sectional study of sanitary irregularities reported by health inspectors of Minas Gerais in the form of risk notification and risk situation sheet 2019 (*Planilha de Notificações de Riscos e Situações de Riscos* 2019). The frequencies found for each type of irregularity were determined and ordered. **Results:** The most commonly found irregularities are, in decreasing order: Documentation/Quality Assurance issues; Inadequate infrastructure; Organization and Hygiene irregularities; Equipment irregularities, including preventive maintenance and calibration; Failure in product quality; Human resources, and waste management issues. All of these irregularities have varying degrees of potential health risk, even though they are often subject to the same course of action, educational and/or coercive, by the Health Surveillance. **Conclusions:** The knowledge of the main irregularities found in the inspected establishments is a highly relevant information for health inspection for the purposes of territorial diagnosis, optimization of the work process and to guide the education and instruction actions, in order to allow an effective intervention of the services in these problems.

KEYWORDS: Health Surveillance; Health Inspection; Health Risk

RESUMO

Introdução: A fiscalização sanitária verifica o cumprimento de normas e regulamentos técnicos visando segurança e qualidade. A Vigilância Sanitária de Minas Gerais possui um sistema de notificação de situações de risco sanitário que possibilita a coleta sistemática e análise de dados relativos às inspeções sanitárias. Esses dados são usados para identificação do risco sanitário no território e consequente definição de ações. **Objetivo:** Determinar as irregularidades mais frequentemente encontradas durante as inspeções sanitárias realizadas em Minas Gerais. **Método:** Estudo transversal das irregularidades sanitárias declaradas por fiscais sanitários de Minas Gerais nos formulários relativos às inspeções, inseridas na Planilha de Notificações de Riscos e Situações de Riscos 2019. As frequências encontradas de cada tipo de irregularidade foram determinadas e ordenadas. **Resultados:** As irregularidades mais comumente encontradas, decrescentemente, são: problemas de Documentação/Garantia da qualidade; infraestrutura inadequada; irregularidades de Organização e Higiene; irregularidades em equipamentos, incluindo manutenção preventiva e calibração; falhas na qualidade dos produtos; recursos humanos; e problemas de gerenciamento de resíduos. Todas essas irregularidades têm graus variados de potencial risco sanitário, mesmo que estejam, muitas vezes, sujeitas às mesmas medidas, educativas e/ou coercitivas, por parte da Vigilância Sanitária. **Conclusões:** O

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conhecimento das principais irregularidades encontradas nos estabelecimentos inspecionados é uma informação de alta relevância para a fiscalização sanitária para um diagnóstico territorial, otimização do processo de trabalho e para orientar as ações de educação e instrução, de forma a permitir uma efetiva intervenção dos serviços nesses problemas.

PALAVRAS-CHAVE: Vigilância Sanitária; Inspeção Sanitária; Risco Sanitário

INTRODUCTION

The beginning of health surveillance practices in Brazil was amalgamated with the medical needs of the population at a time when the country was still a colony of Portugal.[1] Over the years, standards have been published and helped shape Brazil's health surveillance as it is today. In this sense, Law n. 6.437, of August 20, 1977,[2] stands out, as it defines the violations of federal health legislation and establishes their respective sanctions, in addition to the procedures of the administrative-health process and the so-called Unified Health System Law (SUS). Law n. 8.080, of September 19, 1990,[3] in turn, provides for the conditions for health promotion, protection and recovery, the setup and functioning of the corresponding services, and other measures, from which the best known concept of health surveillance was coined:

> a set of activities capable of eliminating, reducing or preventing health risks and of intervening in health problems arising from the environment, production, and circulation of goods, and the provision of services of interest to health. It includes the control of consumer goods that are directly or indirectly related to health, and comprises all stages and processes, from production to consumption, and the control of the provision of services that are directly or indirectly related to health.

Its work includes control activities like licensing, health inspections, and monitoring, which aim to ensure that the establishments comply with the applicable standards.[4] Establishments can achieve the compliance required by health inspections by adopting what is known as Good Practices. Brazil's Health Surveillance Agency (Anvisa), created in 1999 by Law n. 9.782, of January 26,[5] defines Good Manufacturing Practices (GMP) as a set of established procedures that address carefully created and revised production practices, ranging from product development and the purchase of inputs and components, through the production process, storage, to the marketing of products, including monitoring the maintenance of quality requirements when in possession of the consumer (post-market surveillance).[6] In essence, this concept does not differ from those adopted for other types of establishments (Good Clinical Practices, Good Medicine Handling Practices, Good Food Handling Practices, and more).

In fact, Good Practices are procedural guidelines designed with the objective of achieving a certain standard of identity and quality of a product and/or service that consider, in general, four main points to be assessed: critical control points and personnel practices; facilities; general equipment requirements; and production controls.[7] Its broad scope of work and its objective mean that compliance (or non-compliance) with Good Practices is closely related to health breaches. This is because the work of health surveillance is based on the same risks and hazards that these procedures intend to suppress in the processes.[8] Evidence of this is the fact that many technical regulations mention Good Practices in their own names, like the Technical Regulation of Standardized Operating Procedures applied to Food Producing/Industrial Establishments, the Checklist of Good Manufacturing Practices in Producing Establishments/Food Manufacturers (Joint Board Resolution — RDC n. 275, of October 21, 2002),[9] the General Guidelines for Good Drug Manufacturing Practices (RDC n. 301, of August 21, 2019),[10] the Requirements of Good Operating Practices for Dialysis Services (RDC n. 11, of March 13, 2014),[11] among others.

Health inspections verify the application of Good Practices in the form of compliance with technical standards and regulations and encourages improvement with a view to enhancing the safety and quality of services, production processes, and products of interest to health.[4]

To deal with the increased decentralization of health surveillance initiatives in the Brazilian state of Minas Gerais (MG) and monitor the work done by municipal health surveillance bodies, the state health surveillance agency has implemented an instrument whose application enables the identification of health risks and the design of a plan to mitigate/eliminate risk factors.[12]

Reports of risks and risk situations at the Health Surveillance agency of Minas Gerais

In 2012, the Health Surveillance Supervisory Board of the Health Department of Minas Gerais, through the Vigi-Risco Technical Group, created an online form for reporting health risks found in inspections, to be filled out by municipal and state health inspectors.[13] This form, called Risk and Risk Situation Reporting Spreadsheet, was made available on the FormSus platform, a tool for creating forms within the scope of DATASUS and designed to expedite, structure, and qualify data collection and sharing online.[14]

Forms were initially filled out on a voluntary basis, but in 2016 the edition of the resolution of the Bipartite Interagency Commission (CIB) — SUS/MG n. 2.418, of November 17,[15] made it compulsory and it became one of the indicators of the Health Surveillance Actions Monitoring Program (indicator 21).

As a result of the decision, the inspectors/health authorities who work in the state of Minas Gerais must fill out the aforementioned

form after every inspection in the several types of establishments subject to health surveillance. The length of the form depends on the characteristics of the establishment and the conditions found during the inspection — its shortest version has 18 questions whereas the full version has 163 questions, of which the vast majority are objective.

The questions are divided between data identifying the inspecting party and the establishment; characterization of the establishment according to the three areas of health surveillance: food, health and health-related services, and medicines and counterparts; situation found when checking the adoption of Good Practices and approaches taken.

Despite having the characteristics of a questionnaire, the tool is always mentioned as a form, and features annual improved versions, with different access links. The first access presents 16 questions that can be broken down according to the given answers. Since some of these questions are specific to some types of establishments, the total number of questions (163) is hardly ever answered in the same inspection.

Although the form has specific questions for some types of establishments, based on technical regulations of Anvisa or of the state of Minas Gerais, it is a standard tool of the supervisory board. Despite the wealth of data from various different establishments, these establishments are eventually levelled off, which means that, in practice, the data generated will be representative of their classes, but they do not allow detailed views of each establishment or the differentiation of establishments according to particularities like size, types of processes, administrative arrangements, etc.

After the specific questions have been answered, there are questions about proposed and/or performed interventions. One of these questions is about whether or not irregularities were found in the establishment during the inspection. If the inspector declares that any irregularity has been found, a question is added to the form so that the inspector can add details about that irregularity. In this objective question, non-compliant items were categorized by the Vigi-Risco Technical Group into seven types of possible irregularities, plus the option "Other". The "Other" option additionally presents an open field for typing in cases where the inspector believes that none of the predetermined options matches the irregularity.

In each option of type of irregularity, there is an example of related non-compliant items to facilitate the classification by the person responsible for filling out the form, according to the Chart.

It is important to note that these options only become available once the irregularity has been declared, but there is no maximum number of options that can be checked. Any number of options can be checked, and this was the variable collected and analyzed by this study.

Implementing these reports enabled the creation of a historical series of data, which is fundamental to monitor risk situations. In addition, they instruct indicator 21 of the aforementioned Health Surveillance Actions Monitoring Program. This also fulfills item I of Article 17 of Law n. 13.317, of September 24, 1999 (Minas Gerais State Health Code),[16] by enabling the consolidation, analysis, and interpretation of essential health-related data.

Based on the data obtained in the 2019 Risk and Risk Situation Reporting Spreadsheet, which contains all the forms of health inspections done in the state of Minas Gerais and declared in

Chart. Categories of health irregularities and examples of related non-compliant items, as presented in the options of the question "What is the type of irregularity found?" of the Risk and Risk Situation Reporting Spreadsheet, once the inspector reports an irregularity in the health inspection.

Type of irregularity	Examples of non-compliance in each type of irregularity
Physical structure	Irregularities in floors, ceilings, walls or other structures; ventilation and/or lighting problems; structure incompatible with approved architectural design; absence/non-approval of architectural design (when required); among others.
Organization/Hygiene	General untidiness or untidy environment; presence of dirt; presence of objects in disuse or incompatible with the activity; among others.
Product quality	Expired products; unidentified or incorrectly identified products; products stored incorrectly; among others.
Documentation/Quality Assurance	Absence of a health permit, expired health permit, absence of documents/certificates like location permit, certificate of pest control, water tank cleaning record, manual of standards and routines/SOP, PGRSS; among others.
Human resources	Absence of PPE; incomplete or inappropriate PPE for the activity; absence of records of training, immunization and/or periodic examinations (if necessary); among others.
Equipment, including preventive maintenance and calibration	Absence of equipment required for the activity or for the environments (refrigerators, autoclaves, hand hygiene accessories, fire extinguishers, etc.), malfunctioning equipment; absence of preventive/corrective maintenance; absence of calibration and/or validation records (if necessary); among others.
Waste management	Incorrect disposal of products; absence or small number of trash cans/containers suitable for the type of waste discarded; trash cans/containers placed in inappropriate places; absence of PGRSS in place; among others.
Other	Only irregularities that do not belong to any of the categories above, objectively described.

Source: Prepared by the authors, 2020.
SOP: standard operating procedure; PGRSS: Health Service Waste Management Plan; PPE: personal protective equipment.

2019, the present study aimed to determine the most common irregularities found and, by communicating the results, allow more effective health surveillance intervention for their regularization.

METHOD

This is a cross-sectional study that used the 159,325 records made by municipal and state health inspectors in the Risk and Risk Situation Reporting Spreadsheet as a data source. The period chosen was from February 1, 2019, to January 31, 2020, which corresponds to that in which the records address the type of irregularity found during the inspections. These details about the type of irregularity began to be entered into the form in 2019, which led to the restriction in the period we considered for this study. This information enabled us to categorize the irregularities and calculate their respective frequencies. This cut reduced the sample of analysis to 100,156 forms. Because of the criteria established by the work organization of each health surveillance body, we could not make inferences regarding the percentage of establishments inspected under the terms of indicator 21 of the Health Surveillance Actions Monitoring Program.[15] In other words, there is no correspondence between the number of forms and the number of existing establishments, since the same establishment may have been inspected more than once.

RESULTS AND DISCUSSION

The received database contained 159,325 reports. We selected those that declared having found any irregularity, in a total of 100,156 (62.86%). However, in the data record, we found that despite declarations that an irregularity had been found, two of the records did not discriminate the type of irregularity, so they were also eliminated.

The final object included 100,154 reports that, in addition to declaring the existence of irregularities, informed what type of irregularity it was.

Routine health inspections aim to determine whether or not an establishment under health control meets legal requirements, but these inspections do not always present the level of compliance with the legislation or provide a critical judgment of the analyzed items.[17]

Without assessing the criticality of the requirements, the analysis of the indicators is reduced to compliant/non- compliant and fails to reveal the real risk associated with them. Viterbo et al.[17] also defined the existence of potential risk and classic risk, in that classic risk includes probabilities whereas potential risk is related to ongoing events and their possible effects. Potential risk is the one most commonly dealt with by health inspections, and relating the inadequacies—which effectively make up the determined risk—by their most common frequencies and associations enables monitoring and comparing various objects under the control of health surveillance.

Despite this limitation, the analysis of reported irregularities becomes more relevant when it is not restricted to data from only one establishment, but includes all the available information generated during health inspections to allow for better assessment of potential risks.

In the survey conducted in this study, the distribution of inadequacies occurred according to the quantities shown in the Table. It is important to highlight that it is possible that more than one type of irregularity is declared in the same record. For this reason, the percentages found show the relationship of this item only with the total number of records and not with the other requirements, since the sum of these occurrences, in percentages, would exceed 100.00%.

The most commonly found irregularity is related to Documentation/Quality Assurance. This class includes, for example, absence of a health permit, expired health permit, absence of documents/certificates like location permit, certificate of pest control, water tank cleaning record, manual of standards and routines/Standard Operating Procedure (SOP), Health Service Waste Management Plan (PGRSS), among others. In a study by

Table. Quantitative responses to the irregularities and their type, as stated in the 2019 Risk and Risk Reporting Spreadsheet, in decreasing order of occurrence.

Types of irregularities	N.	%*
Documentation/Quality Assurance	66,190	66.09%
Physical structure	45,610	45.54%
Organization/Hygiene	29,158	29.11%
Equipment, including preventive maintenance and calibration	22,507	22.47%
Product quality	16,258	16.23%
Human resources	14,128	14.11%
Waste management	15,858	13.84%
Others	6,103	6.09%
Total reports	100,154	100.00%

Source: Prepared by the authors, 2020.
*The types of irregularities are independent variables, and the relative frequencies should be considered only in relation to the total number of records, with no minimum or maximum parameter of occurrences.

Barbosa and Costa,[18] the examination of documents is the most used instrument in the health safety operationalization process. In part, the high frequency of inadequacies in this requirement can be explained by the concentration of attention on this instrument, and the underutilization of other tools available, like monitoring indicators and those based on adverse events (pharmacovigilance and technovigilance, for example).[18,19]

Relying on documentation is a long-standing trend in the history of health surveillance. Lucchese explains[20] that the federal regulation (as occurred between the 1940s and the 1970s) took an eminently normative approach, because regulating manufacturers and their products was of the utmost importance. The inspection component was not structured efficiently and technical knowledge was eventually used in a notary-like manner, based only on documents. The perpetuation of this model, in which inspectors focus their attention on the available documentation, contributes to and possibly explains the fact that this is the most frequently reported irregularity. Nevertheless, today, the system quality assessment involves understanding that the previous practice, with its notary-like and bureaucratic nature, does not guarantee good results nor does it meet the needs of society. Therefore, a new form of assessment is necessary.[21]

The second most frequently found type of irregularity was that related to infrastructure requirements, for example, irregularities in floors, ceilings, walls or other structure components; ventilation and/or lighting problems; structure incompatible with approved architectural project; absence/non-approval of architectural project (when required); among others.

Structural changes usually need investment and may take a long time to come about, so maybe this type of inadequacy requires solutions that can only be implemented in the long-term. Although infrastructure failures can compromise the quality of the service or product and put users, consumers, and workers at risk,[22] it is important to consider its frequency also in light of the aspects of the inspection.

Giunta and Lacerda,[23] in a study on health inspections in hospitals, associated technical training with organization and the execution of specific services. They also stated that structural aspects stood out in the inspections, which may suggest that since inspectors are more familiar with structural aspects, this type of inadequacy is more easily identifiable. It is known that a plan that takes into account the activities to be conducted in the sizing and specification of structures can avoid functional and aesthetic problems.[24]

In the form, Organization/Hygiene irregularities are exemplified by general untidiness or untidy environments; presence of dirt; presence of objects in disuse or incompatible with the activity; among others. These irregularities rank third in frequency of responses. A workflow is usually determined by someone who is knowledgeable about the production process and who can promote its application in the establishment.[25] We can infer that the lack of knowledge about these processes limits the assessment of inadequacies by the inspectors, since the wide range of economic activities subject to health control makes it difficult for someone to have all the knowledge needed to assess the risks associated with the respective production processes.

The fourth most common group are irregularities in equipment, including preventive maintenance and calibration, defined by the absence of equipment required for the activity or for the environments (refrigerators, autoclaves, hand hygiene accessories, fire extinguishers, etc.); malfunctioning equipment; absence of preventive/corrective maintenance; absence of calibration and/or validation records (if necessary); among others. According to Monteiro and Lessa,[26] adapting equipment and its manufacturers to technical regulations encourages qualitative improvements in products and manufacturing processes.

Regarding the fifth most common type of irregularity—product quality—the impact on the health of potential consumers stands out. We must consider that once the products are available on the market, they will also be subject to the scrutiny of those who consume them. The same goes for services.[27] In this sense, by responding to reports, questions, and complaints from the population about products and services, health surveillance also gives an adequate response to real health problems.[28]

Of all the listed irregularities, the three least frequently reported are related to: 1) human resources, exemplified by the absence of PPE; incomplete or inappropriate PPE for the activity; absence of records of training, immunization or periodic examinations, among others; 2) waste management, including incorrect disposal; absence/small number/wrongly placed trash cans or containers; absence of PGRSS implementation; and 3) others, which inspectors themselves could fill out but which is not the intention of this study.

Because of its nature, a health breach can be a health risk to the population and is, therefore, subject to health surveillance measures (both educational and coercive). The identification of the frequency of each of its types enables better detailing of the risks and, consequently, better planning of interventions by health services in an attempt to safeguard the health of the population, including from the point of view of workers' health and protection of the environment.[29,30]

Health surveillance's awareness of the most common managerial, structural, and procedural failures can facilitate service planning, optimize work processes, and guide training activities for technical teams.

CONCLUSIONS

The present study has shown that 66.09% of the irregularities mentioned by the inspectors are in the Documentation/Quality Assurance category. Although the bibliography can explain this finding, we expected that the highest frequency would be in categories related to the production process, *locus* of the health risks that health surveillance should eliminate or minimize.

This finding supports a new perspective in the planning of training for inspectors, who may find it easier to identify documentary and quality assurance irregularities.

This study should be continued to identify the reasons why irregularities related to Documentation/Quality Assurance occur. We can speculate that some of this non-compliance comes from the lack of clarity about the necessary requirements for the exercise of activities subject to health control. Public administration should devise educational strategies to mitigate these problems.

As for the other irregularities found by health inspectors, the determination of their frequencies is information of equally high relevance, especially for diagnosis and planning of actions.

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Authors' Contribution

César DF, Silva PMF - Conception, planning (study design), data acquisition, analysis and interpretation, and writing of the manuscript. Figueiredo SC - Data acquisition, analysis and interpretation, and writing of the manuscript. - Data acquisition, analysis, and writing of the manuscript. Laguardia FC - Planning (study design) and writing of the manuscript. All authors approved the final draft of the manuscript.

Conflict of Interest

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