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Evaluation of the effectiveness of the notification process in the area of health products

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ABSTRACT

In Brazil, health products are subject to health technology and are marketed only after they are registered by regulated companies. It is important to monitor the performance of these products in the market during the post-marketing phase, in an effort to prevent, intervene, and act in response to complaints and adverse events.

Objectives: Evaluate and perform a functional benchmarking to identify best practices in health technology monitoring of health product companies, and determine critical points regarding the execution of health technology assessment programs.

Methods: The sampling of the target population was non-probabilistic and the investigation was conducted with the collection of different kinds of information related to technical complaint (TC) and adverse event (AE) procedures performed by companies that register health products.

Results: A pilot study was performed. After the preparation of a questionnaire, it was applied in a functional benchmarking in 22 medium/large companies that follow-up with consumers of health products.

Conclusions: The questionnaire developed throughout the study proved to be a useful tool for the diagnosis of the degree of implementation of health products monitoring procedures. Company "A" appeared to be meeting what Brazilian legislation requires as a standard procedure for health technology monitoring.

Introduction

Health products are subdivided as a function of their use. They can be classified as diagnostic, therapeutic, hospital medical support, disposable materials, implantable materials, and in vitro diagnostic products [1,2]. The guarantee of safety and efficacy of these products not only depends on the correct implementation of a quality system in production facilities, but also on the fulfillment of technical requirements for sanitary registration and monitoring of products during commercialization [3].

Historically, health risk management began in the United States in the mid of 1920s, in the context of the "medical error crisis," when processes and operating systems focused on prevention, detection, control, and/or elimination of risks that could cause harm to patients [4]. In the pre-marketing review process, it is not possible to predict all failures or incidents in medical products resulting from misuse. It is only through actual use of products that unforeseen security and performance issues can occur. This can be achieved in an effective manner through the implementation of health technology monitoring programs [5–7] or post-marketing controls. It is in the post-marketing phase that monitoring actions are developed, by observing the performance of the product in the market. In this way, health technology assessment is the set of actions necessary to reach these objectives, compulsorily encompassing the studies, analyses, and investigations of the sum of information gathered regarding the performance of a product during the post-marketing phase [6].

The focus of a health technology assessment program is the monitoring of adverse events (AEs; any unwanted effects in humans from the use of products under sanitary surveillance), and technical complaints (TCs; any notification of suspected alteration/irregularity in a product related to technical or legal aspects, and that may or may not cause harm to individual and/or collective health). The occurrence of TCs or AEs may be associated with poor product quality, inappropriate use of product (procedural errors), and factors inherent to the patient/user (in cases of adverse events), as well as factors of the product itself, often already indicated during the registration process.

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Every product registry holder is required to notify health authorities and provide all information related to an adverse event or technical complaint. This is required whenever a failure involving equipment, articles, implants, and/or diagnostic kits occurs, or when a problem that has occurred during the use of a product has been life-threatening or could have resulted in injury or permanent damage to bodily functions or structures [8].

Different tracking mechanisms have been used by various health authorities around the world, but there is a consensus that underreporting still represents a clear deficiency in all systems used. Despite the progress made with computational online systems, the underreporting of AE and TC cases still persists. This makes the development of additional mechanisms, in order to minimize this deficiency, of great importance.

The objective of the current study was to develop and validate a new complementary tool to assist in the evaluation process of health technology monitoring programs. This tool would be used by health product manufacturers in order to minimize underreporting by companies and hospitals, and to evaluate the robustness of current monitoring systems.

Methods

This investigation was conducted by the collection and evaluation of various pieces of information related to AE and TC procedures performed by companies that register health products. The work began with a pilot study in an importer/distributor of health products, which employed 30 individuals and had been in existence for 15 years, the study was conducted during the month of August 2014. Initially, a thorough analysis of the current health technology monitoring program was conducted, followed by brainstorming with employees of the company about the process of AE and TC notification. All questions developed were listed, and those considered appropriate were added to a questionnaire prototype. The purpose of the questionnaire was to serve as a tool for collecting information to be used in an effort to reduce underreporting in health technology monitoring performed by companies that register health products.

Subsequent analysis of the questions previously proposed was conducted with the use of “cause and effect” diagrams or “Ishikawa” diagrams (a tool for representing possible causes that lead to a certain effect [9,10]). This analysis made the preliminary identification of some of the critical aspects of the notification process possible.

In order to avoid creating response bias in the questionnaire, three critical dimensions were identified, which were aspects of the user’s attitudes, knowledge, and behavior. The possibility of open answers were used, according to the Likert approach [11,12], which is composed of a set of assertions followed by a scale between 1 (*Strongly agree*) and 5 (*Strongly disagree*), with 3 (*Indifferent*) representing an intermediate response [11,12].

The order of presentation of the questions was adjusted to follow the logical flow of the technical complaint and adverse event notification process. The questionnaire was designed to be self-applicable and the negative points in attitudes, knowledge, and behaviors were identified. These negative aspects were converted into actions seeking to mitigate these attitudes, knowledge, and behaviors in the face of risk, and new questions were proposed.

The sampling of the target population was non-probabilistic, with a criterion of choice pointing to professionals of companies that work within the sector of importation and distribution of health products. In this sampling model, not all elements of the population had the same chance of being selected [13].

After the preparation of Prototype 2, it was tested in the same company that was used as a case study for Prototype 1, and later validated through its use in functional benchmarking with the participation of 22 medium/large companies, which follow-up with consumers of health products [14]. The benchmarking with Prototype 2 was applied from January to March 2015.

The answers obtained were classified as: SU - sufficient; SA - satisfactory; or IN – insufficient. Those without classification were questions and considered informative. The classification was performed in accordance with promoting, permitting, or conducting underreporting. The classification adopted in the current study follows the studies of Belo [15] and Cruz [16], where a score was created to interpret the results obtained in a research questionnaire.

With this in mind, the present study considered companies with up to 11% of the respondents presenting attitudes/behaviors that could lead to underreporting as satisfactory; companies with between 11% and 20% of respondents with attitudes/behaviors that lead to underreporting as sufficient; and from 33% or above of respondents with attitudes/behaviors that lead to underreporting as insufficient in health technology monitoring system.

Results and discussion

All the work carried out considered as a prerequisite that companies adequately performed health technology monitoring as a matter of good manufacturing practice, and that the product in question was registered with the appropriate authority, which guarantees a minimum of reliability of the process [3,18]. The first group of items that were contemplated in Prototype 1 of the questionnaire sought to establish if the requirements of Good Manufacturing Practices (GMPs), as well as other sanitary requirements, were included in terms of monitoring programs. The concept of sanitary risk was inserted in this first group of items using the concepts described in ISO14971 [18].

After analyzing these aspects, different items were listed and are presented below: (Table 1)

Having obtained the most relevant points in the initial analysis of the legislation and current regulations, the operational procedures of health technology monitoring related to the notification of AEs and TCs in a health product import/distribution company were studied with the aim to complement these laws/regulations with the practical aspects obtained in the previous analysis. After brainstorming with the company’s employees and analysis of the company procedures used for the treatment of AEs and TCs, several questions were added to Prototype 1. In order to select items that were considered in a systematic way (i.e., causes to consequences), an Ishikawa diagram was used to determine whether the different issues listed could or could not be taken as a root cause of non-notification of an AE or TC. With this, new items were proposed to be part of Prototype 1 (Table 2).

Prototype 1 was meant to represent critical points related to the notification process in health technology monitoring, plus the sum of the collected aspects of the sanitary legislation/standardization. To analyze whether the previous issues included in Prototype 1 were potential root causes for underreporting or non-notification, an Ishikawa diagram was again used (Fig. 1).

After applying the Ishikawa diagram in the questions raised thus far, the first version of Prototype 1 was obtained. Each question was then analyzed in order to confirm its validity as a critical point that would influence the AE and TC notification process. Prototype 1 was then administered to employees of the company used as the case study. Respondents were a diverse group of high-ranking professionals within the commercial team of the company, the technical nurse, and two sales managers. After administration of Prototype 1, and analysis of the results, some issues were addressed that could lead to omissions during the use of the questionnaire. The following questions were modified:

Table 1
GMP requirements evaluated in Brazilian companies.

GMP and Brazilian regulation
• In internal audits of the company, as the problems encountered may be the source causing complaints or non-conformities reported by customers;
• What is the deadline for filing of claim records and nonconformities;
• There is a process of investigation of the causes of nonconformities;
• The traceability of products distributed on the market is guaranteed;
• How is the mechanism of control of notifications received by the authorized distributor;
• There is the custody of product samples resulting from the TC and AE claim;
• There is access to patient data;
• Knowledge of the product component directly involved in the complaint;
• Investigation of the level of complication of the patient;
• Record of death of the patient;
• Product suffers TC or AE to consider the variables: lot size; quantity that has been marketed; quantity in stock; period of validity and the number of distributors who received the product.
• Identify the record holder;
• To register alteration of the operation of medical product;
• Processes applied to risk management in the company;
• Criteria for acceptability of a risk;
• Actions in the control of risk;
• After-sales and product risk mapping.

Table 2
Suggested questions for the questionnaire obtained after the case study, analysis of company procedures and use of the Ishikawa diagram with the company's case study staff.

The target product notification must be classified according to its degree of risk.
• Do you perform manufacturer identification of TC or EA target products?
• Was the target product of the notification a sterile product?
• How often is the reason for the technical complaint identified?
• Your company has a procedure for treating sample TC or AE target products.
• Is it knowing and identifying the technical cause of a TC or AE important in the techno-surveillance process?

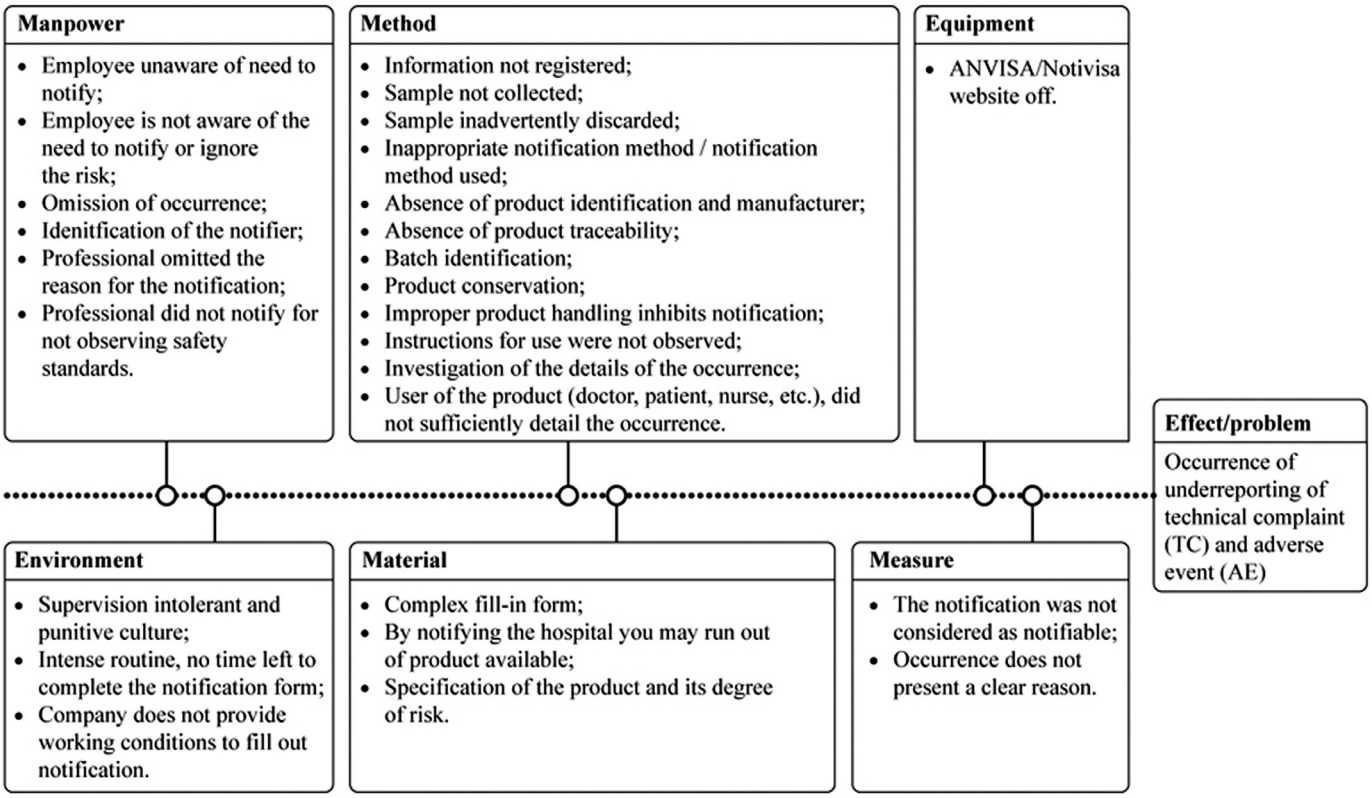

Fig. 1. Ishikawa diagram for root cause assessment for underreporting and non-reporting.

Table 3
Result of the case study.

Concept		Questions												
Notification	1	7	22	33	30									
	SA	SU	IN	IN	SA									
Degree of risk	4	6	10	21	23	24	37							
	SA	IN	IN	IN	SU	IN	SA							
Sample	15	26	32	36										
	IN	IN	SU	IN										
TC & AE	3	8	9	12	14	17	19	20	27	29a	29b	31	38	39
	SA	AS	SA	SA	IN	IN	IN	AS	IN	IN	IN	SU	IN	SA
Product/equipment	11	13a	28											
	SA	AS	SA											
Manufacturer	5	13b	35a											
	SA	SU	IN											

IN Inssuficient SA Satisfactory SU Sufficient

Question 2a) Have you ever had a TC or AE notifications? 2b) If so, how often? a) Once, b) Two, c) Three times, d) Four times, or e) Other. This answer was modified to Other: _____times.

Question 5) The process of identifying the manufacturing company related to the last TC or AE of a product was: a) Very easy, b) Easy, c) Normal, d) Difficult or e) Very difficult. This question was broken down into two questions: How often does the manufacturer of the product related to the last TC or AE have one of these instances occur? a) Always, b) Almost always, c) Almost never, d) Never, or e) I do not know. The other question was: Have you experienced difficulty in the TC and AE notification process? a) Yes, b) No, c) I do not know.

Question 7) A sample of the product triggering the complaint (TC) or adverse event (AE) is available for analysis. a) Yes, b) No, or c) I do not know, modified to: A sample of the product triggering the complainant (TC) or adverse event (AE) is available: a) Always, b) Almost always, c) Sometimes, d) Almost never, and e) Never.

Question 24) Does the product covered by the notification have special storage conditions? a) Yes, b) No, or c) I do not know, was broken down into two separate questions. First: Does the product covered by the notification have special storage conditions? a) Yes, b) No, or c) I do not know. The second question was: Where applicable, the special storage instructions for a product are respected a) Always, b) Almost always, c) Sometimes, d) Almost never, and e) Never.

The modifications performed on Prototype 1 gave rise to Prototype 2. This questionnaire was then re-administered to the case study company, using the same previous respondents.

Results were tabulated and questions were grouped into obeying the concepts notification, degree of risk, samples, TC and AE, product/equipment, and manufacturer. For each concept, questions were divided into those of knowledge, attitudes, and behaviors. This was done in order to show if, in terms of health technology monitoring and risk of underreporting, knowledge and information are reflected in attitudes and behaviors that decrease or increase the risk of underreporting.

The concept that presented the least number of insufficient answers was that of samples, followed by the degree of risk (Table 3). Insufficient responses to the sample concept point to the fact that, at the time of receiving a notification, many respondents have problems with the product sample, which is an important part of the process of analyzing a TC or AE. The most common report was an absence of a sample of the product that triggered a TC or AE. This occurrence was correlated with a lack of knowledge on the part of the employee about the need to have the sample in the process of recording and investigating TCs and AEs. The large number of unsatisfactory responses to the concept of the degree of risk was also due to a lack of knowledge, which affects the attitude of the notifier.

Benchmarking

The final version of the questionnaire was applied in the form of benchmarking [19] in 22 companies, with eight companies providing individual responses and 15 participating from a pool on an internet survey site (Survey Monkey), as these companies were located in different cities. Most of the respondents were composed of senior technical managers, quality managers, and CSCC (Customer Service Call Center) attendants or sales representatives. The groups with the greatest resistance to participation were the CSCC attendants and sales representatives.

Respondents took an average of seven minutes to complete the questionnaire. The benchmarking questionnaire was administered over a period of two months. Company “A” in Table 4 appears to be meeting what Brazilian legislation requires as a standard procedure for techno-surveillance. However, when participants were asked if a sample of the product that caused the TC or AE was available (question 26), the answer was “Sometimes.” Most likely caused by asking the hospital or clinic, and the product not being made available. This indicator of benchmarking is important in determining cause. By sampling the product related to the TC or AE, a manufacturer can determine if the product is faulty or if other factors are at play, since previous research has indicated that 63% of the failures with medical products are due to human error [20].

All the participants (100%) reported insufficient responses to concepts within the knowledge dimension. The statement “When

Table 4
Distribution of IN responses from the benchmarking (pool) in companies A through E in the state of São Paulo.

Concept	Dimensions	Questions X Companies
		COMPANY A
Sample		Question – answer
	Knowledge	26: 100% sometimes.
		18: 50% always, 50% sometimes.
TC & AE		Question – answer
	Knowledge	17: 50% often, 50% sometimes.
		29a: 50% sometimes, 50% often.
		38: 50% often, 50% almost never.
		COMPANY B
TC & AE	Knowledge	Question – answer
		17: 100% sometimes.
		38: 100% almost never.
		COMPANY C
Notification		Question – answer
	Knowledge	1: 100% no.
		7: other uninformed.
		33: 100% (other) 6 involved.
	Attitude	22: 100% never.
		COMPANY D
TC & AE		Question – answer
	Knowledge	29a: 100% almost never. 38: 100% sometimes.
		COMPANY E
TC & AE		Question – answer
	Knowledge	38: 100% no.
		COMPANY F
Degree of risk		Question – answer
	Knowledge	23: 50% no and 50% yes.
		24: 50% yes and 50% do not know.
	Attitude	6: 50% always and 50% almost never.
		COMPANY- São Paulo
TC & AE		Question – answer
	Knowledge	17: 20% always, 27% often, 53% sometimes and 67% almost never.
		29a: 27% often, 33% almost never and 40% sometimes.
		38: 33% yes, 20% no, 40% do not know and 7% they did not answer.

receiving a TC or AE, the reason for the occurrence is clear" and "Knowing the degree of risk of the products I work with is important" were those that were most likely to be answered insufficiently. Question number 38, a question concerning knowledge of the degree of product risk ("Did you have trouble classifying the product for this notification?"), resulted in an unsatisfactory answer by 100% of the companies. This result suggests that participating companies were not aware of the risks posed by products that they carried. Of the participating companies, 43% stated that the reason for a TC or AE was unclear at the time of notification (question 17). In the process of handling a complaint, knowing the reason for the occurrence is important for the entire investigation process. Good adherence to the complaint process can increase patient safety and decrease the number of patients affected [21–28]. The reason for the occurrence (whether a TC or AE) is one of the first pieces of information relevant to the process; this information allows for the evaluation of hypotheses that can possibly explain the failure (i.e., whether the failure is due to a technical problem or human error).

Already in the first application of the Prototype 2 (i.e., in the same company of the case study), it was observed that TC and AE obtained the highest number of unsatisfactory responses. This pattern was repeated in benchmarking, demonstrating that this concept is critical for the health technology monitoring process [17].

Concepts of samples, notification, TC, and AE were the ones that presented the greatest discrepancy in questions involving knowledge. All participating companies had unsatisfactory items for knowledge issues, which points to a need for training.

Therefore, it is necessary to apply greater awareness-raising measures and continuous training so that companies can have a global standard when conducting the health technology monitoring process [16,29,30].

The questionnaire developed through the current study, applied in the case study, and then in benchmarking, proved to be a useful tool for the diagnosis of the degree of implementation of the health technology monitoring procedures in health product companies.

Conclusions

Studying Brazil's health legislation, it was possible to analyze which points imply a greater risk in terms of notifications of deviations. The legal structure was based on deviations that have already occurred, others that may occur, and potential sanitary risks.

The evaluation of the participants' responses goes beyond the text of the legislation. These are additionally considered because the attitudes and the behaviors of employees can impact the execution of sanitary requirements. While regulations exist, and are updated whenever necessary, the ways in which each professional and company applies the regulations in their routine and in the organizational context may influence the underreporting of health technology monitoring and health risk.

The present study allowed us to identify that attitude and behavior dimensions play a crucial role in increasing the risk of underreporting of TCs and AEs in health products. The concepts samples, notification, TC, and AE were the ones that presented the greatest discrepancy in issues involving attitude and behavior dimensions.

The developed questionnaire, through case study application and benchmarking, proved to be a useful tool for the diagnosis of the degree of implementation of the health technology monitoring

procedures in health product companies. The questionnaire may also be applied in the behavior assessment processes of TC and AE notification procedures, to validate notification systems, and in determining the robustness of the structure to support variations that occur due to differences in individual risk analysis. Therefore, in instances where the notifier can appropriately guide the conduct, risk can be minimized.

CRediT authorship contribution statement

Luciana Ferreira Mattos Colli: Methodology, Data curation, Formal analysis, Writing - original draft. **Luiz Cláudio Rodrigues Pereira da Silva:** Writing - review & editing. **Valeria Pereira de Sousa:** Formal analysis. **Marcelo de Padula:** Methodology, Data curation, Formal analysis, Writing - original draft. **Lucio Mendes Cabral:** Data curation, Formal analysis, Writing - review & editing.

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Supplementary material

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