Original Article

Technical complaints submitted to the Regulatory Health Notification and Investigation System

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RESUMO

This study aimed to evaluate technical complaints submitted to the Regulatory Health Notification and Investigation System between 2006 and 2014 through cross-sectional, quantitative, documental research of a secondary public database. It was identified that, of the 245,940 notifications put forward, 109,311 referred to technical complaints. The Southeast region presented the highest information submission (53.5%) and the North presented the greatest difference in quantity of notifications between states (coefficient of variation = 159.2), followed by the Northeast (coefficient of variation = 124.8). Most of the cases of notifications were on medical articles (53.09%) with equipment being the most notified product (19%). Risk to patient health was identified in 56,777 cases, with the highest frequency being in regard to materials of low or medium risk. *Sentinela* Network hospitals were the principal sources of notifications. In the analyzed period there was a gradual annual increase in the number of technical complaint notifications, especially regarding medical articles used in invasive procedures.

Descriptors: Product Surveillance, Postmarketing; Equipment Safety; Nursing; Patient Safety.

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INTRODUCTION

Technological and scientific development in the health environment and its potentially harmful effects raises the necessity to monitor the quality of products available on the market. However, even the most rigorous premarket processes cannot predict failures in healthcare products, since it is only during use, in real circumstances on a large scale, that unforeseen rare events and problems can be identified[1-2].

Therefore, the Health Regulator established the Postmarket Health Regulation (*Vigilância Sanitária Pós-Comercialização*), or Vigipós, with the premise of developing sensitive strategies for the detection of technical complaints and adverse events during work activities. A technical complaint (TC) is characterized as a presumed or confirmed deviation in quality detected in the company or product, in legal or technical terms, with the possibility of individual or collective harm; while an adverse event (AE) is damage to individual or collective health caused by routine use of a product, despite the technical norms of the manufacturer being respected[3-5].

Avoidable harm to the patient is a serious public health problem, and research indicates that such an incident may have already overtaken heart disease as the principal cause of death in the United States, considering under-reporting that occurs even in developed countries[6].

Multicentric studies estimate that approximately 10% of patients admitted to tertiary health units are victims of AEs related to materials used in healthcare, and approximately 60% of the cases result from avoidable factors.

In Brazil, in 2011, according to the Hospital Information System (*Sistema de Informação Hospitalar*) of the Unified Health System (*Sistema Único de Saúde*), 7.6% of hospitalized patients suffer some kind of AE, with 66.7% of cases being avoidable and with a 40% mortality rate. These are astonishing numbers, to the extent that they infer a level of lethality similar to that resulting from AIDS, mammary neoplasia or car accidents[7-8].

Moreover, besides the individual repercussion for the health of the user, AEs provoke considerable financial losses through increasing the length of hospitalization of the individual for additional treatment for the harm caused by the AE, or through judicial indemnities[8-10].

Given this panorama, adequate detection and management of deviations in quality through TCs are decisive factors for the prevention of AEs and their complications. One of the principal tools used to this end are TC and AE notifications submitted to the Regulatory Health Notification and Investigation System (Notivisa)[1].

Notivisa is an on-line platform that systematizes, investigates and manages reports of TCs and AEs provided by healthcare services, self-employed professionals and institutions holding product registration. It receives information on materials under health regulation in the following categories: technovigilance, pharmacovigilance, hemovigilance and biovigilance[11].

Use of this system is essential to increasing the efficiency and efficacy of healthcare services aiming at the recovery of individuals with minimization of harm and risks to well-being. As such, monitoring, analysis and interpretation of technical complaint notifications provides advancement in the production of materials used in medical care, while encompassing the area of research in information systems used in healthcare management.

Therefore, this study proposes to respond to the following research question: which characteristics were identified in the technical complaints submitted to *Notivisa* in the period from 2006 to 2014? The objective of this study was to evaluate the technical complaints submitted to *Notivisa* in the period from 2006 to 2014.

METHOD

This is a cross-sectional, quantitative, documental study, resulting from analysis of a public database on TC notifications submitted to *Notivisa* in the period from January 2006 to December 2014. The year 2006 was selected considering the implantation of Notivisa.

The following variables were analyzed: year of notification, Brazilian state and region, category (medication, medical article, medical equipment, cosmetic, vaccine and immunoglobulin, sanitizing product, reactant kit for *in vitro* diagnosis and agro-toxin) and type of product (equipment for gravitational infusion of parenteral solutions, disposable syringes, surgical gloves etc), classification (product with an allegation of a deviation in quality, product with an allegation of being unregistered, company with an allegation of being without authorization to operate, allegations of other irregular practices and allegations of falsified product) and situation (concluded, collating, under analysis, under investigation, sent, analysis by the company), category of the notifier and classification of risk in reference to product categories or medical article. Data collection occurred between July and October 2015 and was conducted by the leading researcher.

The variables "category of the notifier" and "classification of risk" were regrouped. For the first variable, the categories were: *Sentinela* Network, self-employed professional, hospital with a patient safety nucleus; the other notifiers were grouped into the category of "others". For the second variable (classification of risk), three categories were decided upon: low/medium risk, mixed risk and high or maximum risk.

The data from the *Notivisa* reports was transcribed to Microsoft Excel spreadsheets, on which descriptive analysis of absolute frequencies was carried out, with presentation of measures of central tendency (mean) and dispersion (standard-deviation and coefficient of variation).

For further data analysis, a report on the number of *Sentinela* hospitals present in each Brazilian state in 2014 was requested from *Notivisa*. Moreover, a search was conducted on the site of the Brazilian Institute of Geography and Statistics (*Instituto Brasileiro de Geografia e Estatística* - IBGE) to ascertain the total population of each state in the same year. Based on this information, two indicators were proposed, which, despite being initial indicators, supply a panorama of the situation of notifications based on certain specific characteristics.

According to *Notivisa*, any citizen may report a TC, therefore, the first indicator is a coefficient of TC, considering the total number of TCs divided by the total population in the same period, multiplied by 10^n. The second indicator is a mean index, considering the total number of TCs by the total number of hospitals in the *Sentinela* Network in Brazilian regions.

For analysis of the difference between Brazilian regions regarding notifications, according to classification of risk, the chi-squared test was conducted using Bioestat 5.3.

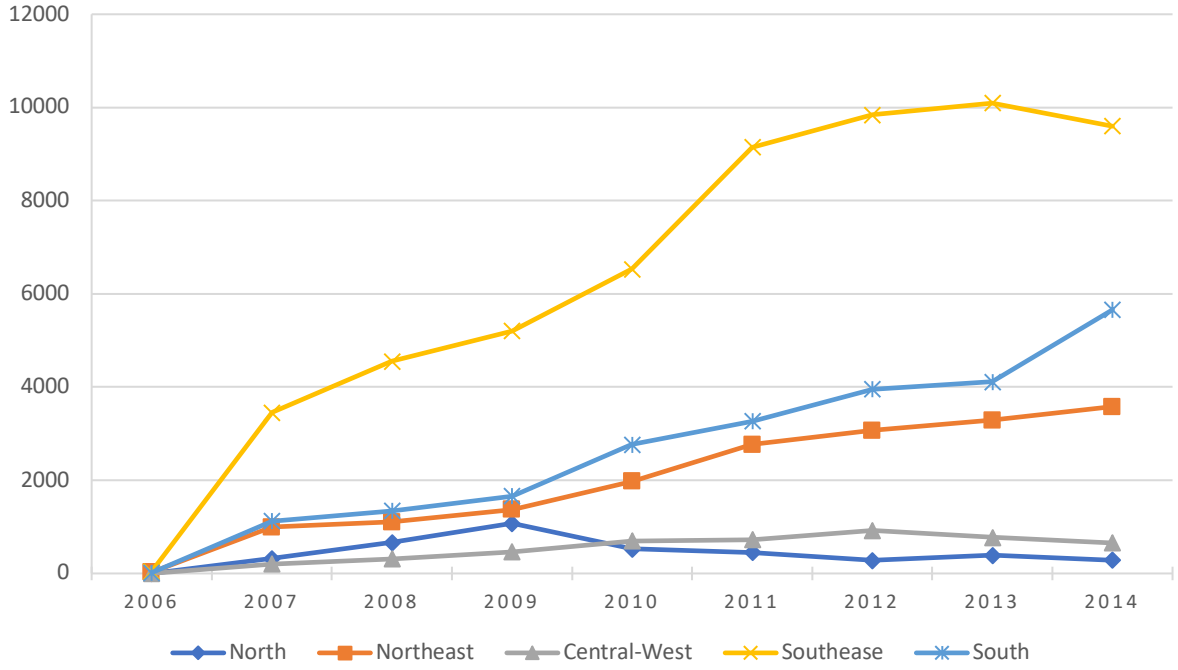
This study project was approved by the Research Ethics Committee of the State University of Londrina-PR, under protocol nº 1356669.

RESULTS

A total of 245,940 notifications were forwarded to *Notivisa* in the period from 2006 to 2014. Of these, 109,311 (44.4%) referred to TCs. Gradual growth of this type of notification in Brazil was observed for this period, evolving from 88 cases in 2006 to 19,783 in 2014.

Among the regions of Brazil, the Southeast most contributed to the forwarding of information to the Health Regulator, with 53.5% of the notifications. In the North, the highest number of notifications was in 2009, with 1,076 reports, declining over the following years; the Central-West region had the highest number of notifications in 2012 (923) (Figure 1).

Figure 1: Distribution of the number of technical complaint notifications by region, per year, submitted to the Regulatory Health Notification and Investigation System (Notivisa).



In the Southeast, the highest numbers of notifications were from the states of São Paulo and Rio de Janeiro; in the South, the two states with the highest number of notifications were Santa Catarina and Paraná.

On the other hand, Roraima and Amapá were the states with the lowest number of TC reports. The North presented the greatest instability of notifications among the states, followed by the Northeast (Table 1).

Regarding products liable to notification, it was found that the most significant portion in this category were medical articles, with 53.09% of the cases, followed by medication, with 40.30%, and medical equipment, with 3.65%, as demonstrated in Table 2.

Among the medical articles, the seven products with the highest frequencies of TC notifications on *Notivisa* were: equipment (17.95%), disposable syringes (10.45%), surgical gloves (9.68%), catheters (6.17%), compresses (3,79%), probes (3.59%) and disposable needles (2.71%).

In relation to classification of notifications sent to *Notivisa*, the majority were classified as allegation of deviation in quality (95.18%), followed by allegation of other irregular practices (2.87% of the cases). Regarding the situation of these notifications on the system, 41.43% had been concluded and 58.57% were under analysis by Anvisa.

In the analysis of the notifiers, it was verified that the three most responsible for reporting and forwarding TCs were hospitals in the *Sentinela* Network, self-employed professionals and hospitals with a Patient Safety Nucleus (12.3%). It is worth highlighting that this distribution is differentiated, according to region, as it can be

verified that *Sentinela* hospitals are responsible for the highest frequency of notifications in the Southeast, South, North and Northeast (Table 3).

Table 1: Distribution of the number of technical complaint notifications, by Brazilian region and state, submitted to the Regulatory Health Notification and Investigation System. Brazil, 2006-2014.

Region	State	N. of technical complaints	%	Mean (sd)	Coefficient of variation
Southeast	São Paulo	40,161	36.74	14,616 (17,523)	119.9
	Rio Janeiro	10,410	9.52		
	Minas Gerais	7,355	6.73		
	Espírito Santo	538	0.49		
South	Santa Catarina	8,988	8.22	7,969 (1.292)	16.2
	Paraná	8,402	7.69		
	Rio Grande do Sul	6,516	5.96		
Northeast	Ceará	7,609	6.96	2,019 (2.521)	124.8
	Bahia	4,850	4.44		
	Paraíba	1,672	1.53		
	Pernambuco	979	0.90		
	Alagoas	960	0.88		
	Maranhão	913	0.83		
	Rio Grande do Norte	654	0.60		
	Piauí	383	0.35		
	Sergipe	148	0.13		
Central-West	Distrito Federal	3,167	2.90	1,194 (1.332)	111.5
	Goiás	741	0.68		
	Mato Grosso do Sul	613	0.56		
	Mato Grosso	254	0.23		
North	Pará	2,589	2.37	571 (909)	159.2
	Amazonas	518	0.47		
	Tocantins	430	0.39		
	Acre	246	0.22		
	Rondônia	158	0.14		
	Amapá	30	0.02		
	Roraima	27	0.02		

Source: Regulatory Health Notification and Investigation System, 2006-2014.

Table 2: Distribution of the number of technical complaint notifications by product/motive, submitted to the Regulatory Health Notification and Investigation System. Brazil, 2006-2014.

Product/Motive	Technical complaint	
	N	%
Medical article	58,032	53.09
Medication	44,054	40.30
Medical equipment	3,993	3.65
Cosmetic	1,287	1.18
Sanitizing product	998	0.91
Reactant kit for *in vitro* diagnosis	817	0.75
Vaccine and immunoglobulin	129	0.12
Agro-toxin	01	0.00
Total	**109,311**	**100.00**

Source: Regulatory Health Notification and Investigation System, 2006-2014.

Table 3: Distribution of the number of technical complaint notifications by region and category of the notifier, submitted to the Regulatory Health Notification and Investigation System. Brazil, 2006-2014.

Notifier	Southeast	South	Central-West	Northeast	North
	N (%)	N (%)	N (%)	N (%)	N (%)
Sentinela Network	35,521(60.7)	11,197(46.8)	1,101(23.0)	10,256(56.45)	3,155(78.9)
Self-employed professionals	6,951(11.8)	2,835(11.8)	1,042(21.8)	2,929(16.1)	452(11.3)
Hospital with PSN**	6,188(10.5)	3,560(14.8)	467(9.7)	313(17.2)	144(3.6)
Other notifiers	9,804(16.7)	6,314(26.4)	2,165(45.3)	1,853(10.2)	247(6.1)
General Total	**58,464(55.4)**	**23,906(21.8)**	**4,775(4.3)**	**18,168(16.6)**	**3,998 (3.6)**

Source: Regulatory Health Notification and Investigation System, 2006-2014.

Although the Southeast presents the highest frequencies of TC notification and the highest number of *Sentinela* hospitals, the highest TC coefficient was found in the South. On the other hand, in the North, even with a lower number of *Sentinela* hospitals, the mean number of TC notifications was the third highest of the Brazilian regions, only lower than the means of the Southeast and the South (Table 4).

Table 4: Distribution of the coefficient of technical complaint per inhabitant and of the notification rate by hospitals in the *Sentinela* Network according to regions that submitted notifications to the Regulatory Health Notification and Investigation System. Brazil, 2006-2014.

Region	TC	Inhabitants	TC Coefficient	STC/SN	RSH	Mean TC/SNH
Southeast	58,464	85,339,316	0.68	35,521	103	344.9
South	23,906	29,074,721	0.82	11,197	43	260.3
Northeast	18,168	56,200,315	0.32	10,256	46	222.9
Central-West	4,775	15,285,867	0.31	1,101	11	100.1
North	3,998	17,305,188	0.23	3,155	12	262.9
Total	**109,311**	**203,205,407**	**0.54**	**61,230**	**215**	**284.8**

Legend: TC: Technical Complaint, STC: Specific Technical Complaint; SN: Sentinela Network; SNH: Sentinela Network Hospitals.
Source: Regulatory Health Notification and Investigation System, 2006-2014.

Considering classification of risk in reference to category of product and medical article (Table 5), 56,777 cases were reported, with the highest frequency being of materials of low or medium risk (83.44% of the notifications). A comparison between the distributions of the technical complaint notifications in the regions followed, according to class of risk of the products, using the chi-squared test, and a statistically significant difference was verified ($p<0.001$).

Table 5: Distribution of the number of medical equipment and medical article technical complaint notifications submitted to the Regulatory Health Notification and Investigation System, according to region and class of risk to health of the products. Brazil, 2006-2014.

Class of Risk of Product / Region	Low / Medium Risk		Mixed Risk		High / Maximum Risk		p-value
	N	%	N	%	N	%	
Southeast	25,040	82.62	507	1.67	476	15.70	
South	9,610	84.49	75	0.65	1,688	14.84	
Northeast	9,012	84.68	78	0.73	1,553	14.59	0.000
North	2,235	90.41	8	0.32	229	9.26	
Central-West	1,478	74.57	41	2.07	463	23.36	

Source: Regulatory Health Notification and Investigation System, 2006-2014.

The Southeast, South and Northeast regions obtained similar distributions when comparing risks, varying from 82.62% to 84.68% of the notifications in the category of low/medium risk, and from 14.59% to 15.70% for

high/maximum risk. Despite having a lower absolute frequency in relation to the South, Southeast and Northeast, the Central-West region proportionally generated the highest number of notifications in the category of products considered high/maximum risk (Table 5).

DISCUSSION

Technological evolution and the constant development of products used for patient care demands effective regulatory measures in healthcare to guarantee the health and safety of those that will handle and/or consume these products. Besides the benefits, excessive use of technology brings iatrogenic potential, through new individual and collective risks, challenging world health regulation and control systems[12].

Activities aimed at monitoring technical complaints and adverse events are not restricted to Brazil. Numerous countries, such as the United States of America (USA) and Members of the European Union, also focus on notification activities as a strategy to analyze deviations in quality and minimize harm, having envisioned this scenario many years ago[13].

The US adopted one of the most rigorous health control systems, this being the responsibility of the Food and Drug Administration (FDA), linked to the US Department of Health and Human Services, monitoring medication (human and animal), cosmetics, medical equipment, biological materials, products derived from human blood, foodstuffs (both human and animal) and food supplements. The FDA was founded in 1862, with the current designation in force since 1930, with the objective of controlling the quality of the abovementioned items and guaranteeing individual and collective safety in the commercial market of said materials[14].

In the USA, two guiding processes can be seen, which encompass testing and research requirements for registration, in the Premarket phase, and follow up of products available on the market, in the Postmarket phase. Strategies are deployed to scientifically evaluate the relationships of adverse events and potential risks involved in the use of a determined product, which permits feedback from healthcare teams during analysis, revision and registration revalidation[14].

In the European Union (EU), the body responsible for executing health regulation activities is CHAFEA (Costumers, Health, Agriculture and Food Executive Agency) in partnership with the EMA (European Medicine Agency). These agencies conduct their activities from the perspective of promoting collective and individual health and safety of patients, minimizing the occurrence of adverse events, through assessment and investigation of reported incidents, besides publicizing reports and warnings when necessary. This system enables the correlation of information between the competent national authorities and the companies responsible for a determined material, providing early corrective action[14].

In the data analysis, it was possible to identify a progressive increase in the number of TC notifications since implantation of *Notivisa,* in 2006, which reinforces the legitimacy of this health regulation strategy. Studies carried out in the period from 2006 to 2013 confirm the growth in TC reports as, in 2006, 10,543 occurrences were reported, reaching 15,228 cases in 2008 and becoming even more evident in 2013[10-11,15]. In contrast, other studies demonstrate oscillations between 2007 and 2009, with a fall of up to 14.5% in notifications reported in 2009[16-17].

Although the analyzed data demonstrates a gradual increase in the number of reports, the possibility of under reporting should be subjectively considered, since there was a significant variation in the number of notifications during this period. There is also the possibility of some occurrences having been investigated and concluded by state or municipal organs of health regulation and therefore not included in the *Notivisa* system[18].

In fact, even notifications of compulsory investigation in reference to AEs, such as those involving death, permanent injury or serious temporary injury, will only be investigated if it is possible to identify the alleged product and the holder of its registration. Moreover, it is necessary to provide evidence characterizing causality, which emphasizes the necessity for the notifications to be complete and coherent. A study demonstrated that in 53% of the events reported to a hospital unit there was no information as to signs and symptoms presented by the patient and, in 49% of the cases, the injuries caused by the AE were not described[10]. Another study found that, in 2009, around 61% of the notifications did not contain data on the occurrence, making it difficult to provide follow up in these cases[16].

In contrast, it is such that in many institutions a culture of safety has been fostered, with the development of strategies for the acquisition of higher quality healthcare products being promoted. Furthermore, professionals have been trained to be constantly monitoring materials in order to identify those with the potential to offer risk to the users or staff[19].

Regarding the Brazilian regions and states, the Southeast, South and Northeast were those that most contributed to the reporting of information. However, a study[20] revealed that in 2007 the municipality of Belém, located in the North, accounted for 7% and 22.1% of the TC and AE notifications, respectively, putting it as the fifth Brazilian capital to report TCs and the second regarding AE.

Considering the coefficient of variation in respect to demographic distribution, it was observed that the South presents greater homogeneity of notifications between its states, with the lowest coefficient of variation among Brazilian regions. Although the Southeast is the biggest notifier of TCs, significant heterogeneity was found among its states in reference to the irregular distribution of the *Sentinela* Network, there being 61 units in the state of São Paulo and only one unit in Minas Gerais. On the other hand, the North, which has the highest coefficient of variation, presents a high discrepancy between its states, especially between Pará and Roraima, which made 2,589 and 159 notifications, respectively, during the study period. This divergence may once again reflect high rates of under reporting, given that in both states there are only four units of the *Sentinela* Network[18].

Between 2006 and 2011, 118,106 reports of TC or AE were submitted to *Notivisa*, with 37,696 related to medication; 29,880 to medical articles, 19,105 to blood and its components and 27,406 to intoxication[9-10]. It can be observed in the isolated analysis of the notified TCs for this period that medical articles lead the occurrences, followed by medication[2,4].

In the present study, it was identified that infusion equipment was responsible for the highest number of TC notifications. Said result is similar to other studies[10,17] in which this article received the most notifications for TCs and AEs. Damage to the structure of the equipment or its packaging can cause serious harm to the patient given that it is used for invasive procedures. As such, it is further supposed that the professionals that used this material identified the technical failures as more serious and, therefore, tend to notify said failures with greater frequency. Furthermore, it can be highlighted that this piece of equipment constitutes one of the most significant

medical articles used in hospital routine and, despite having a relatively low unitary commercial, its ample usage generates significant financial impact when analyzed on a large scale[11,21].

Regarding the type of TC, it was found that most cases involved products with an alleged deviation in quality, similar data having been found in another study, in which 97.10% of TC notifications were connected to an alleged deviation in quality and only 0.5% were related to inappropriate use of the product[12].

From analysis of the available studies[11,16], a large portion of the companies holding the registrations (10.10%) present healthcare products with unsatisfactory quality, since 60.80% of these materials presented multiple notifications[16].

It is worth highlighting that the use of products with a deviation in quality also reflects on the hospital burden, given that direct and indirect costs with health supplies impact on 35% to 45% of the institution's general budget[3]. As such, it is the responsibility of the company holding the registration to guarantee product quality, correct and prevent recurrence of identified failings and/or propose design alterations so as to guarantee user safety, in accordance with the requirements of "Good manufacturing practices of Medical Products"[22].

Most of the reports submitted to *Notivisa* are still being processed and, in accordance with the seriousness of the case, an investigative process was triggered. Notifications that are not immediately investigated are maintained on a database until an analysis of tendency demonstrates their importance, or there is sufficient increase in the number of notifications to trigger the opening of an inquiry[16-17].

Healthcare institutions exercise a crucial role in the consolidation of intra-hospital health regulation and the *Sentinela* Network is the protagonist in the reporting of information to *Notivisa*[2,12]. In 2010, this network was distributed throughout Brazilian territory with approximately 26 units in the North, 55 in the Northeast, 16 in the Central-West, 107 in the Southeast and 43 in the South. It was responsible for 59.8% of the notifications, followed by 14.3% by self-employed professionals and 8.3% from hospitals[10].

Sentinela hospitals perform an essential role in the monitoring of products available on the Market, given that they are qualified to detect TCs and AEs. However, there are regions where the process of implementing these units requires improvement, such as in the Central-West, which still relies significantly other sources for the reporting of information. Despite the North not being the most significant notifier, it uses the *Sentinela* Network as its principal observatory, proving its effectiveness even in less favorable environments. This network contributes promoting the national panorama and, at some moments, the world panorama of market supplies, enabling each collaborating hospital to take on corrective and preventative actions that promote the minimization of individual and collective risks[16].

Reflecting further on the effectiveness of the implantation of the *Sentinela* Network in some regions, it can be observed that the Southeast remained in the lead regarding the average rate of TCs per Sentinela hospital, with 103 units distributed among the highest Brazilian population. Nevertheless, the North, which has only 12 units, presented the second highest mean number of notifications, followed by the South, with 43 units, which demonstrates the importance and the commitment of the network in the most diverse environments.

Considering classification of risk regarding product categories and medical articles, in the present study it was found that most of the notified products were classed as low or medium risk. These results are similar to

those found in the literature, in which products of medium risk were responsible for a large part of TC notifications, followed by those classed as maximum risk[22].

Similarly, a study[16] identified that 72% of the notified products presented medium risk to patient health and safety. Among these, 33.80% were represented by equipment, 7.20% by syringes, 4.80% by gloves, 4.80% by probes and 3.30% by needles. It was also found that 4.80% of the products were classified as maximum risk to the health and safety of the patient and those that handle the products.

It is worth highlighting that studies of this magnitude are pioneering, as publications in this area remain scarce, which instigates refinement of new studies and more sensitive indicators for analysis of the real impact of TC notifications at a national level. It is also necessary to investigate under reporting – which is more ostensive where implantation of the *Sentinela* Network is not effective – besides creating indicators that represent the true panorama of the commitment of all the professionals involved in the process of monitoring the quality of healthcare products[2,11].

CONCLUSION

This study demonstrated a gradual increase in the number of notifications in Brazil, consolidating the system as a form of monitoring products subject to health regulation. It can be observed that *Vigipós* demonstrated insight in planning a strategy such as *Sentinela*, even though some regions are still in the incipient stages of this process, remembering the importance of critical analysis of the national health context.

Among the products susceptible to notifications, medical products stand out for the highest number of notifications, medical equipment being the article with the highest TC frequency. Regarding the situation of said notifications on *Notivisa*, the majority were being investigated or analyzed by *Anvisa*.

Notifications of technical complaints to *Notivisa* demonstrate as relevant for generating an indicator of quality, and even guaranteeing better healthcare products on the market and improved safety for patients and healthcare professionals, besides providing orientation in decision making. It is therefore necessary to implement strategies stimulating professionals involved in care provision to adhere to CT notification reporting, thus contributing to reducing the occurrence of under reporting.

It is worth mentioning that the importance of the notification process resides in the fact of enabling recognition of non-compliances, which can generate both TCs and AEs, and that prevention of their occurrence should be considered a priority of all those involved in this process, from product development to product use.

As such, it is hoped that this study may contribute to evoking good safety practices among healthcare professionals and it is suggested that further studies are conducted to investigate other factors involved in the TC notification process, such as number of healthcare institutions, hospital beds and healthcare professionals, so as to assist in the development of more sensitive indicators for TC notification in the Brazilian scenario.

The limitation of this study lies in the difficulties related to research with secondary data sources, such as under reporting of technical complaints. On *Notivisa* the notifications are spontaneous and depend on action by the institutions. Therefore, it is necessary to conduct constant campaigns raising the awareness of health managers and workers as to the notification of technical complaints and adverse events.

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