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EPIDEMIOLOGICAL PROFILE OF TECHNICAL COMPLAINTS AND ADVERSE EVENTS IN TECHNOVIGILANCE REPORTED BY PROFESSIONALS OF AN INTENSIVE CARE UNIT

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ABSTRACT

Objective: To identify the epidemiological profile of technical complaints and adverse events in technovigilance reported in an Intensive Care Unit of a Belém Hospital. **Methods:** This is a descriptive, cross-sectional, retrospective epidemiological study with a quantitative approach. We collected 16 samples of technical complaints and adverse events notifications from a total of 12 products registered by the Risk Management in the Intensive Care Unit of Hospital Ophir Loyola in 2017. **Results:** Of the 16 samples of notifications collected, 12 (75%) were related to technical complaints and 4 (25%) related to adverse events. The products that most reported complaints of technical complaints were: disposable needle, multipath equipment, disposable glove and hypodermic syringe, where each one of them had 2 complaints records (12.5%). The item with the highest occurrence among adverse events was the adhesive tape with 2 reports (12.5%). **Conclusion:** Among the limitations of the study are the few studies that demonstrate the epidemiological profile of products with notifications of technical complaints and adverse events in technovigilance. Another limitation found in the study was the description of the quality deviation presented in the product, which made it difficult to systematize the data.

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INTRODUCTION

Technovigilance is understood as the system of adverse events and technical complaints of health products in the after-sales phase with a view to recommending measures to ensure the protection and health promotion of the population. These products include equipment, apparatus, material, article or system for use in medical or dental or laboratory applications, intended for prevention, diagnosis, treatment, rehabilitation, diagnostic product for in vitro use, among others (Brasil, 2010). The occurrence of adverse events represents a serious financial loss. UK and Northern Ireland, or lengthening hospital stay due to Adverse Events costs about £ 2 billion a year and the National Health System spending on AE- related litigation and over £ 400 million a year (Mendes *et al*., 2005). From the release of the report of the Institute of Medicine (IOM) for Erris Human, the subject patient safety gained relevance.

This report is based on two AE assessment surveys of retrospective chart reviews conducted in hospitals in New York, Utah, and Colorado. The report found that about 100,000 people die in hospitals each year from adverse events in the United States. This high incidence results in a higher mortality rate than attributed to patients with HIV positive, breast cancer or roadkill (Kohn *et al*., 2000). It is noteworthy that there are few scientific publications related to technology activities in Brazil and most of them produced by health authorities (Manfredi, Menocin and Santos, 2010). To identify the epidemiological profile of technical complaints and adverse events in technovigilance reported in an Intensive Care Unit of a Belém Hospital from January to December 2017.

MATERIALS AND METHODS

This is an epidemiological, descriptive, cross-sectional, retrospective study with a quantitative approach. Sixteen

samples of technical complaints and adverse events were collected from a total of 12 products registered by Risk Management at the Intensive Care Unit of Ophir Loyola Hospital, in the municipality of Belém do Pará, from January to December 2017. Data collection was performed through a survey of adverse event notifications and technical complaints that occurred in the Intensive Care Unit of the Ophir Loyola Hospital, registered by the Risk Management. A data collection instrument developed by the author himself was used for this purpose. The data obtained were stored in a database for later processing in the Microsoft Excel 2016 software spreadsheet and demonstrated through tables. Simple descriptive statistical analysis using the G test was used to detect the significance level of the samples using the BioEstat 5.3 software. to a significance level of 95% (p <0.05). This study maintained the anonymity of individuals who suffered an adverse event and of the professionals who made the notifications registration, thus preserving the confidentiality and confidentiality of the data to which they had access, this respected the basic principles of bioethics, obeying the norms of the resolution. No. 466/12 of the CNS / MS. The study was approved by the Research Ethics Committee (CEP) of the Ophir Loyola Hospital - protocol nr. 201875808, CAEE: 94308218.9.0000.5550, with exemption from the informed consent form and the term of commitment for the use of data and medical records (TCUD). Notification forms duly completed with the date of the notification were excluded, and this must be done from January to December 2017, what type of occurrence was notified, and other legible and consistent information.

RESULTS

A total of 16 samples of notifications were collected between Technical Complaints (QTs) and Adverse Events (EAs) related to Risk Management Technovigilance (GR) at Hospital Ophir Loyola (HOL), with 12 (75%) notifications of technical complaints and 4 (25%) adverse event reports from a total of 12 products, articles, and medical and hospital materials notified by HOL Intensive Care Center (CTI) professionals from January to December 2017, as shown in Table 1. The method used to determine the significance level of the samples was the G test using Bioestat Software version 5.3. to a significance level of 95% (p <0.05). This method was chosen because it is a relatively small number of samples.

Table 1. Distribution of notifications of technical complaints and adverse events related to the number of notifications, Belém - PA, 2019

Variable	Frequency		p-valor
	Nº	%	
Notification			
Technicalcomplaint	12	75	<0.0001
Adverse event	4	25	
Total	16	100	

Source: Risk Management, Ophir Loyola Hospital, 2017.

The products that most reported technical complaints were: disposable needle, multivariate equipment, disposable glove and hypodermic syringe, where each one of them had 2 complaints records (12.5%), and together they accounted for 50% (8) of the notifications. Hospital articles such as urine collection bag (closed system), enteral nutrition equipment, microporous tape and sharps disposal container appear shortly thereafter with 1 (6.25%) complaint each. Regarding adverse events, 4 (25%) occurrences were reported in the period. The item with the most occurrences was the adhesive tape with 2 notifications (12.5%). Then, central venous catheter and MAP device presented only 1 (6.25%) registered occurrence, according to Table 2.

Table 2. Distribution of notifications of technical complaints and adverse events related to medical products, Belém - PA, 2019

Variable	Frequency		p-valor
	Nº	%	
Product			
Technical Complaints			
Disposable needle	2	12,5	
Multipathequipment	2	12,5	
Latexglove	2	12,5	
Hypodermicsyringe	2	12,5	0.1968
Collection bag (closed system)	1	6,25	
Enteral nutritionteam	1	6,25	
Microporous tape	1	6,25	
Sharpsdump container	1	6,25	
Adverse event			
Stickingplaster	2	12,5	
Central venouscatheter	1	6,25	0.3048
PAM device	1	6,25	
Total	16	100	

Source: Risk Management, Ophir Loyola Hospital, 2017.

Regarding the degree of risk, only products with risk grade I (Small Risk) and II (Medium Risk) were reported, and there were no reports of grades III and IV in 2017. Of all 16 samples, 5 (31.25%) were related to Grade I, and 11 (68.75%) related to Grade II, according to Table 3.

Table 3. Distribution of notifications of technical complaints and adverse events related to Risk Degree, Belém - PA, 2019

Variable	Frequency		p-valor
	Nº	%	
Notification			
Grade I – Low Risk	5	31,25	
Grade II – Medium Risk	11	68,75	<0.0001
Total	16	100	

Source: Risk Management, Ophir Loyola Hospital, 2017.

Regarding the reasons that led professionals to make notifications of hospital products, 4 reasons were observed in the notifications of technical complaints and 2 reasons for notifications of adverse events. Among the technical complaints, the present reasons were: Extravasation with 4 (25%) of the notifications, being the most prevalent cause, material fragility and product failure at the time of handling, both presented 3 (18.75%) occurrences, and Finally manufacturing defect with 2 (12.50%) notifications. Among the products that showed extravasation are multivias and enteral nutrition equipment. Among those with fragility were the easily tearing latex gloves. Failed at the time of handling, the needles used in dilutions to prepare medications that clogged with the rubber of the vials. Finally, they presented a manufacturing defect with a syringe that had the plunger still loose with the sealed package and a microporous tape without adhesive. Regarding the reports of adverse events, the damage reported in the period were: skin lesion with 3 (18.75%) episodes recorded, and edema accompanied by hematoma with 1 (6.25%)5 occurrence. Skin lesions were caused by the use of adhesive tape in 2 episodes, and 1 occurrence due to the use of a MAP device, while edema accompanied by Hematoma was caused by the use of CVC, as shown in Table 4.

Table 4. Distribution of notifications of technical complaints and adverse events related to the reason, Belém - PA, 2019.

Variable	Frequency		p-valor
	Nº	%	
Technical Complaints			
Extra vasation	4	25	<0.0001
Fragilidade do Material	3	18,75	
Product failure at the time of handling	3	18,75	
Manufacturing defect	2	12,50	
Adverse event			
Skinlesion	3	18,75	0.0155
Edema and Hematoma	1	6,25	
Total	16	100	

Source: Risk Management, Ophir Loyola Hospital, 2017.

DISCUSSION

Of the 16 samples collected, only 4 (25%) were reports of adverse events related to medical and hospital articles in the period from January to December 2017. In a study conducted at a sentinel hospital in the risk management sector, where 100 notification forms were analyzed, the total notified over three years showed underreporting, failure to fill out the form and lack of information about the event, verifying the lack of knowledge. professionals about the importance of reporting and the need to encourage full reporting of adverse events (Carneiro *et al*., 2011). In this study, technical complaints were predominant among the notifications of the 16 samples studied in the period. A previous Ministry of Health study showed that in 2007, 4.5% of notifications were of adverse events versus an average of 95.5% of notifications of technical complaints (Brasil, 2010).

The highest number of complaints regarding events was evidenced in this research by the proportion of 4 adverse events (25%) versus 12 technical complaints or 75% of the total samples. This difference in the number of notifications between complaints and events is also observed through a survey conducted in a university hospital of the sentinel network in the city of Goiânia-GO, which points out 81% of Technical Complaints notified compared to 19% of the occurrence of events, out of 100 total notifications reviewed (Bezerra *et al*., 2009). In a teaching hospital in the state of Paraná, some of the most commonly reported medical-hospital articles as a technical complaint between 2007 and 2009 were 3-way connectors (5.74%), equipment (9.99%), and syringe (8, 13%) (Gil *et al*., 2015). The UFRJ HUCFF Risk Management (GR) received 203 notifications of quality deviations (technical complaint) and adverse events, in which 13% were from multivariate connections, 9% equipment and 6% syringes (Goés, 2013). The higher incidence of these products is consistent with the findings in the Ophir Loyola Hospital Risk Management (GR) samples in which these same medical-hospital articles appear among those that received the most notifications except for the 3-way connectors, and added the latex gloves.

Overflows, material fragility, product failure at the time of handling, and manufacturing defects were the most common causes of notifications encountered during the investigation of reported complaints and events. A study at a Sentinel Hospital in Belém from 2009 to 2011 found material and packaging problems as the main causes of quality deviation and also found that the most commonly reported products with these and other nonconformities were syringe, equipment, wire suture, urine collector and intravenous catheter (Azulino *et al*., 2013). Manfredi, Menoncin and Santos (2010) have identified that material and packaging problems together account for 45% of total complaints of medical and hospital supplies from February 2006 to May 2008 in a Santa Catarina hospital.

In accordance with RDC Resolution No. 185 of October 22, 2001, medical devices may be classified as Class I, II, III or IV according to the intrinsic risk they pose to the health of the consumer, patient, operator or third party. involved. (11) Thus, in relation to the degree of risk of medical-hospital articles involved in notifications, the results indicated that the medium risk products (Risk Grade II) presented the highest quality deviation, with more than half of the occurrences (Brasil, 2001). Hazard Class II medical products, such as needle, central venous catheter and multivariate equipment, even though they present a lower risk than Class III and IV products, are widely used in hospital routine and are used in various procedures by health professionals, mainly doctors, nurses and nursing technicians, which increases the concern with these articles, as they may cause some health damage (adverse event) not only of users / patients but also of operators / professionals. In the case of procedural gloves, for example, which had only 2 notifications and belong to risk class I, these products are used on a large scale and can pose risks to professionals and clients because according to Vicente *et al* this article has special importance in routine. Health services, as it represents an important barrier between the professional and potential sources of risk of contamination by biological agents and, consequently, of infection (Vicente *et al*. 2011).

Little literature addresses the degree of risk of these products involved in technical complaints and adverse events. In a study on behavior of medical-hospital materials in Brazil from 2007 to 2010, medium-risk products accounted for 67% of technical complaints, followed by low-risk products with 19.5%. Regarding adverse event reports, Grade II products were also the most reported with 43.6% (Vicente and Freitas, 2012). In the study by Sousa *et al*. (2017), on the analysis of notifications in a sentinel hospital, with 171 notifications related to hospital medical articles, performed at HUUFMA, their findings, in short, basically corroborate all the results of this research. , since the data are similar, where most of the notifications were of technical complaints (17 (9.94%) of adverse events and 154 (90.06%) of technical complaints), some of the products that had more notifications were glove. (26.90%), syringe (10.53%), equipment (6.43%) and needle (2.92%), Medium Risk products accounted for 91 (59%) of technical complaints. followed by 56 Low Risk (37%), and product fragility and manufacturing defect appear among the leading causes of deviations reported (46.89% and 42.94% respectively).

Conclusion

It is understood that the objectives of the research were achieved by identifying the epidemiological profile of technical complaints and adverse events, which described the characteristics of notifications, the most incident occurrences identified by Risk Management, and presented the degree of risk. of products that have had reported complaints or events. Among the limitations of the study are the few studies that demonstrate the epidemiological profile of products with notifications of technical complaints and adverse events and

point to the need for further studies to contribute to the identification of new cases of occurrences.

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REFERENCES

Azulino, ACO., Costa, MHA., Carvalho, MN. Moreira, AS., Oliveira, AF., Pinto, ACG., Matos, IP. 2013. Technical complaints made by health professionals related to products used in Sentinela Hospital of Belém - Pará. Rev. Bras. Farm Hosp. Ser. 4, pp. 13-16.

Bezerra, ALQ., Silva, AEBC., Branquinho, NCSS., Paranaguá, TTB. 2009. Analysis of technical complaints and adverse events reported in a sentinel hospital. *Rev. Enferm.* 17, pp. 467- 472.

Brazil. Ministry of Health. National Health Surveillance Agency. 2010. Technovigilance Manual: approaches to sanitary surveillance of health products marketed in Brazil Vol. I, Brasilia, Brazil.

Brazil. Ministry of Health. National Health Surveillance Agency. Resolution. 2001. RDC No. 185 of October 22, 2001 - Approves the Technical Regulation contained in the annex to this Resolution, which deals with the registration, alteration, revalidation and cancellation of the registration of medical products at the National Health Surveillance Agency. Brasília, Brazil.

Carneiro, FS., Bezerra, ALQ., Silva, AEBC., Souza, LP., Paranaguá, TTB., Branquinho, NCSS. 2011. Warning events in the surgical clinic of a university hospital: quality assessment instrument. *Rev. Enferm. UERJ*. 19, pp. 204-211.

Gil, RB., Chaves, LDP., Laus, AM. 2015. Material resource management focusing on the technical complaint. *Electronic Journal of Nursing*. 17, pp. 100-107.

Goes, SMC. 2013. National Patient Safety Program. Risk management / HUCFF. Newsletter. 2, pp. 1-2.

Kohn, LT., Corrigan, JM., Donaldson, MS 2000. To err is human, Vol. I, National Academy Press, USA.

Manfredi, MAB., Menoncin, SM., Santos, TG. 2010. Technovigilance: the quality of health products in a sentinel network hospital. *Lat Am J Pharm.* 29, pp. 626-630.

Mendes, W., Travassos, C., Martins, M., Noronha, JC. 2005. Review of studies evaluating the occurrence of adverse events in hospitals. Rev Bras Epidemiol. 8, pp. 393-406.

Sousa, SS., Pontes, LPP., Maia, JLB., Araújo, HAWP., Rocha, TPO., Diniz, RP. 2017. Technovigilance risk management: analysis of notifications in a sentinel hospital. Nursing Journal UERJ. Pp. 25: 1-7.

Vicente, MG., Freitas, DRC. 2012. Behavior of medical and hospital materials in Brazil from notification data on Technovigilance. BIT: Technovigilance newsletter. 3.

Vicente, MG., Trinity, E., Melchior, SC., Santanna, PC., Pismel, AMCL., Tinoco, ATM., Santos, MMA., Ferreira, PA., Avila, R., Hofmeister, MGSA., Sorgenfrei, RHHH., Modesto, AL. 2011. The importance of technovigilance in the glove regulatory process in Brazil. BIT: Technovigilance newsletter.

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