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Original article

RISK MANAGEMENT REPORTING AND ITS CONTRIBUTION TO PATIENT SAFETY

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ABSTRACT: The present study aimed to identify risk management reporting of products related to technovigilance and pharmacovigilance between 2002 and 2004 and 2007 and 2013. Retrospective, documentary study with quantitative approach. Data were collected from April to August 2014, analyzed and presented using absolute and relative frequency calculations. A total number of 529 notifications were reported. Most notifications occurred in in-patient units: n= 218 (42%). The Technovigilance notification type led with n=494 (93.4%), the subgroup venipuncture had a prevalence of n=218, 41.2%. Defective product corresponded to n=324, 61.2% of the reported events. Regarding the association between sector and notified materials, the venipuncture group, in the Emergency department stands out with n=68 (70.1%). This data contributes to the generation of a quality indicator and to ensure better health products that promote safety to patients and health professionals.
DESCRIPTORS: Risk control; Health care quality assurance; Patient safety; Nursing; Risk management.

NOTIFICAÇÕES DA GERÊNCIA DE RISCO E SUA CONTRIBUIÇÃO PARA A SEGURANÇA DO PACIENTE

RESUMO: Objetivou-se identificar as notificações de produtos a tecnovigilância e farmacovigilância a Gerência de risco entre os anos de 2002 a 2004 e de 2007 a 2013. Trata-se de estudo retrospectivo de análise documental com abordagem quantitativa. Os dados foram coletados no período de abril a agosto de 2014, analisados e apresentados em frequência absoluta e relativa. Identificaram-se 529 notificações. A maior frequência de notificação ocorreu nas unidades de internação n= 218 (42%). O tipo de notificação Tecnovigilância liderou com n=494 (93,4%), o subgrupo venopunção teve prevalência de n=218 41,2%. O defeito do produto apresentou n=324 61,2% das ocorrências notificadas. A associação entre o setor e os materiais notificados destaca-se o grupo de venopunção no setor das Emergências n=68 (70,1%). Estes dados são relevantes para gerar um indicador de qualidade e garantir melhores produtos de saúde que promovam segurança para os pacientes e profissionais de saúde.
DESCRITORES: Controle de risco; Garantia da qualidade dos cuidados de saúde; Segurança do paciente; Enfermagem; Gerenciamento de risco.

NOTIFICACIONES DE LA GESTIÓN DE RIESGO Y SU CONTRIBUCIÓN PARA LA SEGURIDAD DEL PACIENTE

RESUMEN: Estudio cuyo propósito fue identificar las notificaciones de productos de tecnovigilancia e farmacovigilancia a la Gestión de riesgo entre los años de 2002 a 2004 y de 2007 a 2013. Es un estudio retrospectivo de análisis documental con abordaje cuantitativo. Los datos fueron obtenidos en el periodo de abril a agosto de 2014, analizados y presentados en frecuencia absoluta y relativa. Fueron identificados 529 apuntes. Las unidades de internación tuvieron la mayor frecuencia de notificación: n= 218 (42%). El tipo de apunte tecnovigilancia fue superior, con n=494 (93,4%), el subgrupo venopunción tuvo prevalencia de n=218 41,2%. El defecto del producto presentó n=324, 61,2% de las ocurrencias notificadas. La asociación entre el sector y los materiales notificados se destaca en el grupo de venopunción en el sector de las Emergencias n=68 (70,1%). Estos datos son relevantes y pueden generar un indicador de cualidad, además de garantizar mejores productos de salud y promover seguridad a los pacientes y profesionales de salud.
DESCRIPTORES: Control de riesgo; Garantía de cualidad de los cuidatos de salud; Seguridad del paciente; Enfermería; Gestión de riesgo.

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INTRODUCTION

Epidemiological changes, demographic demands, political and economic changes and the development of new technological solutions to health problems increase the complexity of health care services [1]. In this context, the use of new technologies is a key factor in the recovery of health and quality of life of patients

However, technological innovation has generated problems such as indiscriminate and passive acceptance of the least developed countries, poor quality, low professional training, misuse and hospital costs that impact the hospital organizations in Brazil [2].

In pursuit of improvement of the quality of health products, management and monitoring of adverse events in hospital, the ANVISA (Brazil's National Health Surveillance Agency) created in 2002 the Brazilian Sentinel Hospital Network. The network has 193 accredited hospitals that systematically monitor and report adverse events, meeting all the requirements for excellence in reporting adverse events to ANVISA [3-4].

The Sentinel Network is a strategy of the National Public Health Notification and Investigation system – VIGIPOS – to systematically monitor, analyze and investigate adverse events and technical complaints relating to services and products under public health control surveillance, in the post-marketing/post use stage. The Sentinel network acts as an observatory in the health risk management services, and works with the National Health Surveillance System (SNVS) [5]. Each hospital of the Sentinel Network counts on a Risk Management (RM), as a liaison with ANVISA.

Risk Management develops actions within the scope of pharmacovigilance, responsible for the control and surveillance of drugs; hemovigilance, which receives reports on side effects, blood transfusions and blood products; technovigilance, which controls the quality of hospital inputs and equipment, and biovigilance responsible for the reporting of adverse reactions in donors or recipients of cells, tissues or organs used in transplant procedures, grafts, assisted human reproduction and / or advanced therapies [4-5].

Given the important role of Risk Management in the development and maintenance of risk management actions and patient safety, this study aims to identify notifications of technovigilance and pharmacovigilance-related products to Risk Management.

METHODOLOGY

Descriptive, retrospective, documentary study with quantitative approach. It was conducted in the Risk Management sector of a large, high complexity trauma center, of the public network of Recife.

Data was collected through the notification form of the Risk Management department during a 10-year period, as follows: 2002-2004 and 2007-2013. The years 2005 and 2006 were excluded because notification sheet filling was discontinued. The total number of notifications was 529. The sheets contained the following variables: year, materials group, type of notification, place where the event occurred (sector), and group of events.

Because of the wide variety of notified materials, they were divided into groups: 1. Venipuncture materials, which included notifications related to syringes, peripheral catheters, double and triple lumen catheters, adhesive tape, serums and infusion equipos; 2. Probes, drains and cannulas were included in a subgroup composed of endotracheal cannulas, chest tubes, nasogastric, urethral, rectal and aspiration tubes; 3. Surgical materials including surgical gloves, bandages, gauze, bandages, sutures, tweezers, needles, scalpel blades, surgical caps and masks; 4. Equipment and hospital and medical supplies including vacuum cleaners, cervical collars, pincers, sphygmomanometer, colostomy bag, infusion pumps, heart rate monitors, respirators, enzymatic detergents; 5. Drugs included all complaints of medications recorded.

Data collection was performed from April 1 to August 30, 2014 after approval by the Research Ethics Committee of the Hospital Complex (HUOC / PROCAPE), under No 11555912.8.0000.5192.

After collection, data was arranged and analyzed using absolute and relative frequency distributions. The statistical program used for data entering and statistical calculations was the Statistical Package for Social Sciences (SPSS), version 21. Pearson's chi-square test and/or Likelihood ratio test was used to determine the association between two categorical variables. A 5% margin of error was used in statistical tests.

RESULTS

The analyzes performed during this 10-year study resulted in 529 notifications that are arranged in charts and tables. Figure 1 shows that 2010 was the year with the highest frequently of notifications (23.4%), followed by 2009 (17.6%) 2003 (12.5%) and 2011 (12.5%) . The other years had percentages ranging from 3 to 8.6%.

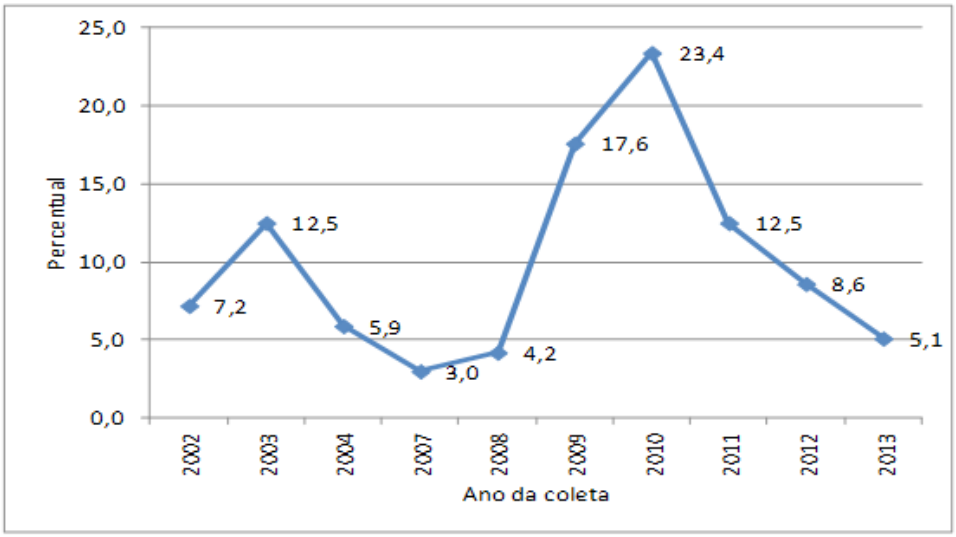

Figure 1 – Absolute distribution of notifications by Risk Management in the 2002-2013 period. Recife, PE, Brazil, 2013

Table 1 characterizes the notifications to Risk Management according to the study variables.

Table 1 – Characterization of notifications to Risk Management according to the following variables: material group, type of notification, sector and type of event (N=529). Recife, PE, Brazil, 2013 (continues)

Variable	N 529	% 100
Materials group		
Venipuncture	218	41.2
Surgical material	173	32.7
Equipment and hospital and medical supplies	78	14.7
Probes/drain and cannulas	21	4
Drugs	33	6.2
Incomplete notification	6	1.1
Type of notification		
Technovigilance	494	93.4
Pharmacovigilance	30	5.7
Sanitizing material	4	0.8
Incomplete notification	1	0.2

Sector		
Various clinics	224	42.3
Surgical ward	134	25.3
Emergency care	98	18.5
ICUs	67	12.7
Incomplete notification	6	1.1
Type of event		
Defect	324	61.2
Leakage	64	12.1
Package	49	9.3
Residue/ dirt/ foreign body	34	6.4
Incomplete notification	22	4.2
Color, consistency and altered odor	20	3.8
Event/ adverse effect /no effect	13	2.5
Shelf life	3	0.6

The most used materials were those in the venipuncture group: n = 218 41.2%, followed by surgical instruments with n = 173 (32.7%) and equipment and medical and hospital supplies, with n = 78 (14.7%). Regarding notification, technovigilance obtained the following percentages of complaints: n= 494 (93.4%). The percentages of notifications of pharmacovigilance and sanitizing products were respectively n = 30 (5.7%) and four (0.8 %).

Regarding the sectors/locations involved, the highest percentage (42.3%) corresponded to the floors, followed by the surgical ward (25.3%) and emergencies (18.5%) and the lowest percentage was observed in the ICUs (12.7%). Regarding the type of event: n = 324 (61.2%), defect and leakage, packaging and waste/dirt/ foreign body obtained respectively n = 64 (12.1%), n = 49 (9.3%) and = 34 (6.4%).

Table 2 shows the association between sector and notified materials, which highlights the main discrepancies: the venipuncture group in the Emergency sector with 70.1% and the surgical ward with 20.9%. The group of surgical materials in the Surgical Ward with 68.7% and the group of support material and furniture in the ICUs with 25.8%. There was a significant association between the two variables (p <0.001).

Table 2 – Distribution of the Group of Materials Notified to Risk Management according to the Sectors (N=517). Recife, PE, Brazil, 2013

Group Material	Surgical ward		Emergencies		Various clinics		ICUs		Group total		P value
	n	%	N	%	n	%	n	%	N	%	
Venipuncture	28	209	68	70.1	93	42.3	27	40.9	216	41.8	p (1) < 0.001*
Probes/drain and cannulas	4	3	5	5.2	6	2.7	6	9.1	21	4.1	
Surgical ward	92	68.7	14	14.4	55	25	10	15.2	171	33.1	
Equipment and Medical and Hospital material	6	4.5	8	8.2	47	21.4	17	25.8	78	15.1	
Drugs	4	3	2	2.1	19	8.6	6	9.1	31	6	
TOTAL	134	100	97	100	220	100	66	100	517	100	

(*): Significant difference at 5%.
(1): Through the test of likelihood ratio.
Note: there were six incomplete notifications related to the group of materials and 6 incomplete notifications related to the sectors.

DISCUSSION

The results of this study showed a considerable growth in the number of events reported in the 2002-2008 and 2009-2013 periods, rising from 170 (32.5%) to 353 (67.4%), respectively. Analysis of the national data recorded at NOTIVISA (System of Notifications for Sanitary Surveillance) showed a gradual increase in the total number of notifications. In 2006 102 technical complaints were recorded; in 2010, 26 997 technical complaints were recorded and in 2013, 38.839 complaints [6]. This fact can be related to the increased implementation of risk management services, with the expansion of the Sentinel hospital network across the country and the dissemination of the advertising campaign of six international goals of quality and patient safety recommended by the World Health Organization, in 2010. However, despite the yearly increase in the total number of notifications, few events were reported considering the complexity of the care provided in the hospital where the study was conducted.

Technical complaints are filed by health professionals when the requirements for the registration or marketing of drug products are not met, or else, when failure to meet quality standards is suspected[7]. Notification of technical complaints and adverse events contributes to the control and prevention of occurrences associated to health problems and hence to the improvement of the quality of these products that will be used by the general population.

Increase in the number of notifications is directly related to educational actions targeted to health professionals. Thus, the Risk Management should be committed to the implementation of actions aimed to encourage notifications [8-9].

However, national and international studies indicate underreporting or non-reporting associated to voluntary notification by health professionals [10-11]. The main challenges in reporting include understaffing and work overload in health facilities, time spent completing the forms, poor understanding of the events and lack of feedback regarding the measure taken [12-13].

Another important aspect is associated to the professionals who work in Risk Management. In order to prevent failures in active search and appropriate completion of notification forms, these professionals need continuing training[14].

Manual notifications create difficulties to the notification process. A study showed that 26.1% of manual notifications had errors related to the use of wrong notification form or misidentification of the adverse event. Also, 49.6% did not determine the severity of the issue, and 36.8% of these hand-written notifications were considered unreadable, and 22.3% had erasures [10].

Regarding the identification of the notifications submitted to Risk Management most concerned Technovigilance with n = 494 (93.4%), and clinical notifications were the most frequent with n = 224 (42 %) followed by surgical ward notifications with n = 134 (25%) of the total complaints recorded.

From 2009 on, the tool used to control notifications was the NOTIVISA. Reports of notifications in technovigilance were not compulsory until 2010 when the Resolution of the Collegiate Board of Directors (RDC) 67/2009 was created [15]. Awareness of the importance of exercising notification is slowly being developed in Brazil.

Thus, over the years medical-hospital articles showed an increasing number of complaints in Brazil: 5,416 complaints in 2009, 7, 070 complaints in 2010, 8,994 complaints in 2011 and 10,225 complaints in 2012, while in the present study, 2010 was the year with the highest percentage of complaints (23.4%), followed by 2009 (17.6%), thus maintaining the same growth rate of notifications registered by NOTIVISA [6] over time.

An important aspect regarding the greatest number of notifications in Technovigilance might be explained by the fact that events not related to professional errors are more easily reported[16].

The present study revealed that Various Clinics was the sector with most notifications. This is probably explained by the higher number of hospital beds and inpatients.

However, it should be stressed that in the surgical ward medical and nursing teams are more involved in risk management practices. These teams add new references to the assessment of the

treatment to be prescribed and the material to be used[17]. The nurses learn how to relate events of the care practice to possible risks arising from the use of materials. Also, the implementation of the safe surgery protocol, which requires checking the operation of the multiparameter monitor prior to anesthetic induction and surgical incision and equipment condition was assessed by the nursing team, contributing to the a higher number of notifications [18].

Regarding the materials group, we found that the venipuncture group accounted for 41.2% of the total technical complaints. In a study that analyzed 393 technical complaints of products, ANVISA revealed that 53.4% of the notifications were related to Equipos (18,9%), Disposable Syringes (11.8%), Catheters (8.3%), Disposable Gloves (6,4%), Surgical Gloves (4.2%) and Tubes (3.8%)[6], which is consistent with our findings.

This group of materials is relevant for high-risk diagnostic and surgical procedures and clinical treatments. Despite being relatively inexpensive and classified as Medium Risk products (Class II), these are widely used products that deserve greater attention from health surveillance, especially in the postmarketing stage [6].

However, the number of pharmacovigilance-related complaints in the referred hospital, considering its size and importance, was below expectations. The profile of notifications concerning products/ reasons provided by NOTIVISA in the 2006- 2011 period was led by the drugs group, as follows: in 2008, with 5,707 notifications, in 2009 (7,602) in 2010 (9,586) and in 2011 with 12,573 notifications [19]. In our study, in turn, nine complaints were recorded from 2002 to 2008, and 24 complaints from 2009 to 2013, indicating the need for educational interventions as a strategy to raise health professionals' awareness of the importance of reporting.

Therefore, health professionals should be able to identify an Adverse Drug Reaction (ADR). ADR is a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function' adverse reactions to medications. Health professionals are supposed to report any adverse events detected [20]. When these events are not reported, valuable opportunities for conducting further studies on drugs related to risks and benefits, drug interactions, route of administration, manufacturing quality, among others, are missed[21].

Regarding the type of occurrence, defective product we obtained 324, 61.2% of the notifications related to structure. An ANVISA report showed 2,906 notifications of products that do not meet the legal requirements(6). Another finding of this investigation was the number of notifications in the venipuncture group, n=68, accounting for 70.1% of the technical complaints in the Emergencies sector. Venipuncture is a key procedure in this sector, allowing more opportunities for observation and assessment of these items. Care in specialized units greatly depends on the safe use of life support materials and equipment, among other procedures that also require effective quality control and maintenance[12].

There were only four complaints related to sanitizing products, confirming that this group involved the lowest number of notifications: according to Brazilian data, there were 48 notifications in 2007, 91 in 2008, 140 in 2009, 215 in 2010, 120 in 2011 and 159 in 2012[17]. Complaints related to sanitizing products include strong smell, less foam and lower concentration than expected.

CONCLUSION

The technical complaints related to technovigilance, materials group of venipuncture and type of occurrence (defects of medical and hospital materials) characterized the notifications of this study.

Postmarketing monitoring of products through technical complaints should be continuous in order to identify intervention needs as well as systematize the actions and measures to be adopted on a timely basis.

Therefore, the strategy of the sentinel hospital met its target concerning health surveillance of marketed products.

One limitation of this study concerned incomplete notifications. We suggest the implementation of computerized and systematized notifications to ensure effective management, as well as raising health professionals' awareness of the fact that risk management is everyone's responsibility and not just the responsibility of managers.

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