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PROFILE OF NOTIFICATIONS OF TECHNICAL COMPLAINTS OF BLOOD BAGS MARKETED IN BRAZIL AFTER PUBLICATION OF THE NEW TECHNICAL REGULATION

PERFIL DAS NOTIFICAÇÕES DE QUEIXAS TÉCNICAS DE BOLSAS DE SANGUE COMERCIALIZADAS NO BRASIL APÓS A PUBLICAÇÃO DO NOVO REGULAMENTO TÉCNICO

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ABSTRACT - Blood bags are risk III-high complexity products designed to collect, store and transfer blood efficiently and safely. The national reference for the analysis of this product is the National Institute of Quality Control in Health (INCQS) - Oswaldo Cruz Foundation, responsible for the preliminary analysis to the registry and control of these products. RDC publication No. 35/2014 replaced Ordinance No. 950/1998, which optimized and validated the methodologies. This study aims at evaluating the profile of

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notifications before and after implementation of the new technical regulation of blood bags in Notivisa System. The research was conducted from 2012 to 2016. The following filters were used: period, product name and type of event (technical complaint). 458 notifications were held and 520 problems were found in the study period. this difference was noted in view that some notifications contained more than one issue related to the product. There were 39 complaints registered in the system in 2012, and 48 in 2013, 92 in 2014, 150 in 2015 and 129 in 2016. The main reasons reported were related to bent and/or broken needles (15.6%), defective seals (10.2%) and extravasation of anticoagulant and/or preservation solution (9.6%). There was a significant increase of notifications in 2015. The study showed that the previous analysis conducted in INCQS is a positive tool for SNVS, but it does not guarantee the sanitary quality. Thus, we highlight the importance of health monitoring for purchasing product with acceptable quality, avoiding part of the notifications.

Keywords: Health Regulation and Inspection. Plastic Bags for Blood Preservation. Information System. Health Surveillance of Health Products.

RESUMO - As bolsas de sangue são produtos de alta complexidade, classificados como risco III, que se destinam a coletar, armazenar e transferir o sangue de forma eficiente e segura. A referência nacional para análises deste produto é o Instituto Nacional de Controle de Qualidade em Saúde (INCQS) da Fundação Oswaldo Cruz, responsável pelas análises prévias ao registro e controle destes produtos. A publicação da RDC nº 35/2014 substituiu a Portaria nº 950/1998, onde as metodologias foram otimizadas e validadas. O objetivo deste estudo foi avaliar o perfil das notificações antes e depois da implementação do novo regulamento técnico de bolsas de sangue no Sistema Notivisa. Realizou-se pesquisa no período de 2012 a 2016. Foram utilizados os seguintes filtros: período, nome do produto e tipo de evento (queixa técnica). No período de estudo foram realizadas 458 notificações e encontrados 520 problemas, pois, por vezes as notificações continham mais de um problema relacionado ao produto. Em 2012, foram realizadas 39 queixas no sistema, em 2013 (48), em 2014 (92), em 2015 (150) e 2016 (129). Os motivos mais notificados foram relacionados à agulha torta e/ou quebrada (15,6%), defeito no lacre (10,2%) e extravasamento da solução anticoagulante e/ou preservadora (9,6%). Em 2015, houve um aumento significativo das notificações. O estudo demonstrou que a análise



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prévia realizada no INCQS é uma ferramenta positiva para o SNVS, mas não garante a qualidade sanitária. Assim, destaca-se a importância do monitoramento sanitário para aquisição de produtos com qualidade aceitável, evitando parte das notificações.

Palavras-chave: Regulação e Fiscalização em Saúde. Bolsas Plásticas para Preservação de Sangue. Sistema de Informação. Vigilância Sanitária de Produtos para a Saúde.

INTRODUCTION

The blood bag, as it is stated by standard ISO 3826-1/2013, is a product that consists of sterile plastic bags, complete with collection tubes, output tubes, transfer tubes, needle for collection and associated containers, which depends on their purpose. They are risk III-highly complex products, in accordance with Resolution RDC No. 185, of October 22, 2001. The product is designed for collection, processing, storage, administration and transportation of blood and blood components efficiently and safely (BRASIL, 2001; ISO, 2013; BRASIL, 2014).

For storing blood fractions, the blood bags can be of dry-type, i.e., blood bags without anticoagulant and/or preservation solution, or with anticoagulant and/or preservation solution. The national reference for analysis of this product is the National Institute of Quality Control in Health (INCQS/FIOCRUZ), responsible for the prior to registry, fiscal and control analysis (VALE, 2010).

The regulatory reference for the control of this product is Resolution RDC No. 35, of June 12, 2014, issued by Anvisa, that replaced Ordinance No. 950 of November 26, 1998 from the Ministry of health (MS), which contains the methods that were evaluated, optimized and validated (BRASIL, 1998; VALE, 2010; BRASIL, 2014)

The quality control of blood bags follows the parameters described in current legislation (RDC No. 35/2014). It is the main legal quality control instrument of blood bags and is related to the main official compendium and international technical standards. This legislation sets out an initial assessment of general aspects by verifying the parameters of transparency, flexibility, strength and compatibility with the content under normal conditions of storage, size, packaging and labelling. It also sets out the verification of collection tubes, needle for collection and output tubes. The evaluation of specific



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aspects is recommended by physical, biological and physicochemical assays (VALE 2010; BRASIL 2014);

Quality control analyses are procedures or assays to check the conformity of the product with respect to the declared information (INMETRO, 2014; INMETRO, 2015). In the National Sanitary Surveillance System (SNVS), the analyses contribute to the quality assessment of inputs, products, environments or even services subject to sanitary surveillance (VISA) (ANVISA, 2010; BRANCO, 2015).

The health products, when used under the recommended conditions and for the intended purposes, should act in a way that does not compromise the health of patients and product operators. In Brazil, the post-market surveillance of health products is designated as technovigilance. The technovigilance unit (UTVIG) consists of a surveillance system for adverse events (EA) and technical complaints (QT) of health products in post-marketing phase, being coordinated by the management of the Nucleus of Management of the National System of Notification and Investigation in Sanitary Surveillance (*Núcleo de Gestão do Sistema Nacional de Notificação e Investigação em Vigilância Sanitária* - NUVIG/ANVISA), which aims to verify the safety and performance to ensure the health protection and promotion (ANVISA, 2010). According to Anvisa Technovigilance Guide (*Manual de Tecnovigilância da Anvisa*), EA is "an unwanted effect in humans resulting from the use of products subject to VISA", and QT consists of a complaint related to the "suspicion of change/irregularity of a product related to technical or legal aspects, which may or may not cause harm to health" (ANVISA, 2010). UTVIG, established in 2001, has made Anvisa responsible for receiving the required reports from health professionals and registration holders of health products in order to submit the publication of alerts, the withdrawal of products from the market and the monitoring of registration revalidation processes (ANVISA, 2010; ANVISA, 2015a).

The product, after receiving the approval of Anvisa/Ministry of health (MS), can be marketed and initiates the post-marketing phase, where unexpected problems can be observed during the registration assessment. It is of utmost importance to gather and assess the information received on a particular product, i.e. perform post-marketing surveillance, since the protection and promotion of the population health are VISA's assignments (BRASIL, 1976; ANVISA, 2010; BRASIL, 2013).

In order to increase post-use surveillance, Notivisa (Notification System for Health Surveillance), a national computerized system, was developed and became available in Anvisa portal, which receives EA and QT notifications related to the use of



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products and services under health surveillance carried out by Sentinel hospitals (which function as services observatory for the management of risks to health in joint and effective action with the National Sanitary Surveillance System (SNVS), companies that hold registrations, health professionals and citizens, in order to minimize the risks and problems associated with the product (BRASIL, 2013)

EA and QT notifications related to products under VISA are received by Notivisa (ANVISA, 2015a). Ordinance No. 1,660, of July 22, 2009, which establishes the notification and investigation system on sanitary surveillance - Vigipós, represented a milestone in the surveillance of EA and QT, and made it possible to obtain better information from EA and QT of products marketed in the country and to subsidize health regulation, since it joined epidemiological and sanitary surveillance through the systematization and integration of notification, research and monitoring mechanisms of EA related to health services and products (BRASIL, 2009a; MORAIS, 2009; ANVISA, 2010; MORAIS, 2011; MORAIS, 2013).

In order to facilitate and expedite the obtainment of information on the performance of products in use, Anvisa deployed in 2002 the Brazilian Network of Sentinel Hospitals (Rede Brasileira de Hospitais Sentinela), formed by teaching and/or high complexity hospitals, to act as observatories of performance and safety of health products, allowing to encourage notifications of adverse events and technical complaints (ANVISA, 2010; ANVISA, 2015a; BRANCO, 2015).

The research is conducted by Anvisa, in accordance with the criteria used for each product and with the severity of cases. If a case is confirmed, the registration holder company needs to take action involving the generation of safety alerts and disclosure to health services and population, in order to preclude or minimize the likelihood of health damage to the population exposed to the product (ANVISA, 2015a).

In 2009, by Anvisa resolution number 67/2009 was published, which provides the technovigilance standards applicable to health product registration holders in Brazil, and thus forced the owners to notify occurrences involving their products. This showed a concern involving the monitoring of post-marketed products, representing extreme importance to SNVS since it allows data collection that contributes to the audit actions and regulatory evolution (BRASIL, 2009b; FEITOZA-SILVA, 2016)

This study aims at evaluating the profile of notifications before and after implementation of the new technical regulation of blood bags in Notivisa System.



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METHOD

A data search was carried out in Notivisa system, involving QTs related to plastic bags received by Notivisa (Figure 3). All notifications related to blood bags registered in Notivisa from 2012 to 2016 were requested to the Management Unit of the Notification and Investigation System on Sanitary Surveillance (Nuvig/Anvisa).

After being electronically received, the notification records were handled using a spreadsheet editor, classified and evaluated using the following filters: year, product name (blood bags) and type of event (QT). The time period from 2012 to 2016 was chosen to carry out this study to assess the impact of the new technical regulation published in 2014. The total number of QTs logged in Notivisa was quantified and subsequently analyzed by year in the period proposed to assess the situation of the products on an annual basis, since during the period of study a legislation was published that modified the regulation of plastic bags in Brazil³. Considering the risk associated, according to RDC No. 185/2001, with the type of products found, the object of study was defined. Thereafter, the grounds of the technical complaints were analyzed and quantified (BRASIL, 2001).

The study was limited, according to the product type, from technical complaints, period and reason. The data on notifications have been exported to an Excel worksheet®, classified and quantified according to the type of product. For that, the following words were used as filters: bag, kit, set and "blood", which provided information on the blood bags that enabled the quantification of their contents, since it is possible to find the product name as a kit, set, etc. Data was organized and evaluated using Excel ®.

Each notification was assessed, identifying the reason to define a profile of QT notifications. The reasons for the technical complaints were individually examined and classified into the following groups: functionality, packaging, aspect, registration and others. Within these groups, the technical complaints were reclassified with greater specificity, and individually, into subgroups, correlating the technical complaint reasons with the conformity criteria established by Resolution RDC No. 35, of June 2014. By identifying and quantifying the problems pointed out, the profile of technical complaint notifications in the period and the most prevalent reasons per year were defined (BRASIL, 2014).



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A request to UTVIG for a study with the object to be studied, for greater scope, was needed to start our research, and therefore, we requested the use of "pockets", "kits", "blood" and "set". The whole study was based on the notifications found in Notivisa related to quantity, and for this reason, the second filter was used for this purpose.

The results obtained were organized into charts and graphs for better presentation and analysis of results.

RESULTS

458 notifications were found in Notivisa related to 520 problems, since some notifications contained more than one issue related to the product. Hence, despite of the high number of QT for these products, we focused on the study of items with greater impact on public health. Then, we analyzed and quantified the reasons of each notification (table 1). The notification is voluntary for health professionals and population, but mandatory for registration holders and health services and, thus, some notifications may have been processed (investigated and completed) by the State or Municipal Sanitary Surveillances without being included in Notivisa (BRASIL, 2009b; ANVISA, 2010; BRASIL, 2010; ANVISA, 2015b).

The descriptor "blood bags" was the one with the largest number of notifications in each year. The other descriptors ("kit", "set" and "blood") presented a similar number of notifications between 2012 and 2016. Between 2012 and 2016, 39 (2012), 48 (2013), 92 (2014), 150 (2015) and 129 (2016) notifications (458 in total) were registered in Notivisa related to technical complaints associated with blood bags.

Table 1 presents the different reasons related to QT notifications about blood bags recorded in Notivisa, during the period of study. The notifications were classified by reasons, in order to minimize gaps and non-uniformity of the notifiers. The proposed topics were defined by quality criteria established in the specific standard.

This classification was of great relevance due to heterogeneity of the notifications and the diversity of the notifying agents. Notifications whose non-conformities did not fit in the stated rankings, or that did not have a clear description of the problem presented, were classified as others.



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Table 1: Technical complaint records related to blood bags from 2012 to 2016

Description of Technical Complaints	Number of notifications					Total	%
	2012	2013	2014	2015	2016		
Functionality							
Disconnected needle	5	7	12	6	6	36	6.9
Bent and/or broken needle	2	11	13	28	27	81	15.6
Defective bag connector	3	0	6	8	6	23	4.4
Defective seal	6	2	0	34	11	53	10.2
Needle obstruction	4	3	0	7	2	16	3.1
Vacuum system damaged	1	1	0	6	1	9	1.7
Defective retractable system (needle)	0	0	6	1	0	7	1.3
Package							
Disrupted plastic package	2	0	10	4	13	29	5,6
Labelling issues	1	1	1	2	5	10	1,9
Aspect							
Collapsed bag	1	1	2	3	1	8	1,5
Blood extravasation	1	5	12	14	12	44	8,5
Extravasation of anticoagulant and/or preservation solution	8	8	13	9	12	50	9,6
Presence of blood clot	1	1	1	0	0	3	0,6
Altered color of anticoagulant and/or preservation solution	0	0	0	8	9	17	3,3
Altered pH and lack of anticoagulant and/or preservation solution	0	1	2	0	3	6	1,2
Presence of holes and microholes in the bag	5	0	2	1	4	12	2,3
Presence of holes and microholes in the collection tube	1	0	1	3	2	7	1.3
Presence of dirt, stain or foreign bodies inside the product	3	1	3	8	11	26	5,0
Others	6	9	17	23	28	83	16,0
Total	50	51	101	165	153	520*	100

*There were, sometimes, more than one type of non-compliance in the same notification, and for this reason, the total number of technical complaints (520) was greater than the total number of notifications registered in NOTIVISA (458).



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Source: Notivisa data. Adapted (2016).

After the classification in 4 groups, notifications were reclassified into 18 sub-groups, based on quality criteria established in specific standard for blood bags, in order to more specifically assess the problems observed and reported by the notifiers, during use.

Based on the classification carried out, it could be noted that the main reasons reported were related to bent and/or broken needles (15.6%), defective seals (10.2%) and extravasation of anticoagulant and/or preservation solution (9.6%) (Figure 1).

Figure 1: Reasons of greater prevalence of technical complaint notifications related to blood bags, per year

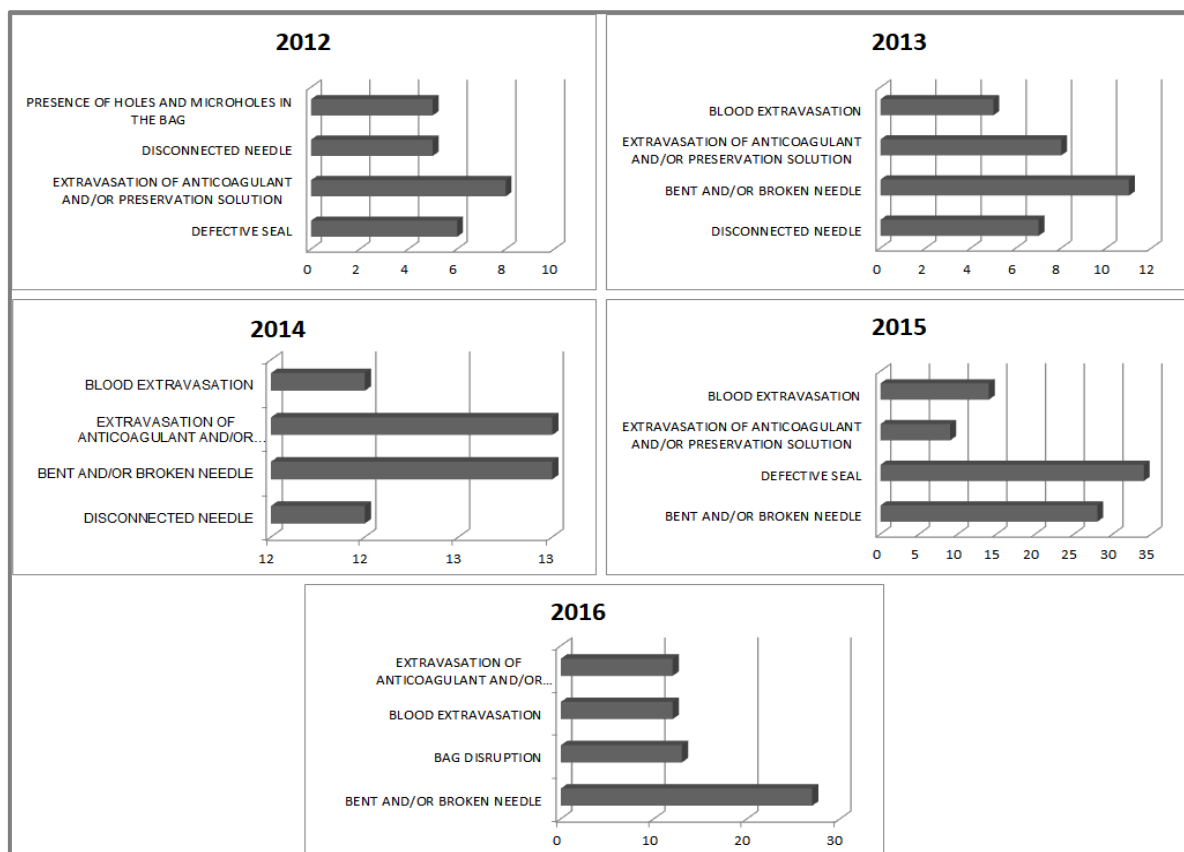


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Source: Notivisa data. Adapted (2016).

DISCUSSION

According to table 1, these non-conformities may point out problems in the process control of manufacturing blood bags, or problems associated with control of manufacturing environments (NICKEL, 2010).

In 2015, the year in which the new technical regulations for blood bags came into force, the number of notifications for this product significantly increased. It was verified an emergence of notifications related to anticoagulant and/or preservation solutions (color changed), which represents a potential risk, and even other problems encountered, such



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as bent and/or broken needle (81), disconnected needle (36) and bag disruption (29), which comprise a risk especially to health professionals that handle the product, in addition to the financial damage that may be caused by product loss, for being a high value product.

With respect to the increase of occurrences in 2015 related to defective seals, a significant decrease of more than 50% was observed in 2016 in the number of notifications in relation to 2015. On the other hand, there was not a remarkable decrease of notifications related to bent and/or broken needles from 2015 to 2016.

The decrease could be related to a possible adequacy of the companies to solve these problems, after the implementation of the new technical regulation. Additionally, it is important to note that the blood bags are risk III products (high risk), according to the classification set forth by RDC No. 185/2001, i.e. these problems should not even show up. An inspection by the responsible bodies and compliance with the acceptance criteria determined by legislation in force is needed (BRASIL, 2001).

Analyzing this bias, we can conclude that the registration holder companies are not complying with the quality criteria set forth, and not even perform a risk management of their products, since the number of notifications in 2016 remains high. With this in mind, the SNVS should monitor, analyze and investigate these quality deviations, even in case of limitations as to the resources needed for taking action in post-marketing analyses, and of structured and accredited laboratories for analysis of these products (BRANCO, 2015; ANVISA, 2010).

It is important to highlight that the registration holder company is responsible for the quality assurance of the product and shall take measures to prevent and avoid recurrence of the failures identified, as well as analyze processing errors, in order to ensure the safety and efficacy of the product to avoid risks to users (BRASIL, 2013).

The participation of health professionals, health services and system users is of paramount importance, and the notification aids in quality monitoring of post-marketing products. The awareness of Notivisa system is necessary, since it promotes integration between VISA and the society, serving as an important tool to help taking preventive measures by SNVS and the company itself (VICENTE, 2012; ANVISA, 2015c; BRANCO, 2015).

CONCLUSION



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Therefore, it was possible to evaluate, in the period of study, the QT notifications related to blood bags before and after implementation of the new technical regulation for blood bags.

The classification provided an individual evaluation of notifications due to the large amount of related problems and the diversity of notifications recorded in the system, which are presented in a non-structured form.

458 QTs were reported in the study period, and 2015 was the year with the greater number of registered notifications. The QTs of higher prevalence were related to bent and/or broken needles (15.6%), defective seals (10.2%) and extravasation of anticoagulant and/or preservation solution (9.6%).

It is worth mentioning that, in 2015, there was a significant increase of "bent and/or broken needle" and "defective seal" notifications, which decreased in 2016. However, the emergence of notifications related to anticoagulant and/or preservation solution in 2015 and in 2016, which in previous years had no record in the system, is worrisome.

The study carried out in Notivisa showed that the previous analysis conducted in INCQS is a positive tool for SNVS, but it does not guarantee the sanitary quality. Moreover, it represents a positive strategy of partnerships with official laboratories. Studies related to QTs and EAs of products of health concern and the implementation of monitoring programs that seek to strengthen post-market surveillance actions are important, these actions being understood as a duty or assignment of all parties of the SNVS. Thus, we highlight the importance of monitoring, that should be continuous and combined with a strategy of appreciation of sanitary official laboratories with information that will certainly reduce the risk to population and guide a strategy for acquisition of products with acceptable quality, avoiding part of the notifications and improving VISA actions.

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