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Panorama of notifications about adverse events and technical complaints related to facemasks

Panorama das notificações de eventos adversos e queixas técnicas em máscaras

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ABSTRACT

Introduction: In the daily routine of Health Professionals, mainly in the midst of the Sars-CoV-2 pandemic, facemasks are important devices; however, there is no post market control for these products. **Objective:** Evaluate the Adverse Events (AE) and Technical Complaints (TC) related to facemasks and respirators, to list and categorize the public health problems involving these products. **Method:** Cross-sectional, descriptive, retrospective and documental study with a quantitative approach, including data from January 2010 to May 2020 available in the Notivisa system. The analyzed data had national coverage and were reclassified, when necessary, according to their category (EA or QT). **Results:** 443 notifications were included in the study containing 519 claims (AE and TC). The data distribution on the analized decade presented an accentuated decrease; the Southeast region had the highest prevalence of claims in Brazil. Most of the notifying companies were health establishments and the highest prevalence of health events found were Adverse Events that affected the user when fixing strips and nose clips (such as detachment of the nose clip and breaking of the fixation straps during use), indicating serious biosecurity problems. **Conclusions:** This study characterized the Adverse Events and the Technical Complaints in facemasks focusing on health promotion and indicating the necessity of sanitary monitoring improvement of the products.

KEYWORDS: Facemasks; Adverse Events; Product Health Surveillance; Pandemic

RESUMO

Introdução: No cotidiano dos profissionais de saúde, principalmente no enfrentamento à pandemia do SARS-CoV-2, as máscaras são artigos de suma importância, porém não existe programa de controle de pós-comercialização para tais produtos. **Objetivo:** Avaliar os eventos adversos (EA) e as queixas técnicas (QT) de máscaras dos tipos cirúrgicas e respiradores, a fim de elencar e categorizar os problemas de saúde pública envolvendo o produto. **Método:** Estudo transversal, descritivo, retrospectivo, documental com abordagem quantitativa, englobando dados de janeiro de 2010 a maio de 2020 disponibilizados no sistema Notivisa. Os dados analisados tiveram abrangência nacional que foram reclassificados, quando necessário, acerca da sua categoria (EA ou QT). **Resultado:** Incluiu-se 443 notificações no estudo, que continham no total 519 reclamações (EA e QT). A distribuição dos dados na década analisada apresentou acentuado decréscimo, sendo a Região Sudeste do país a com maior prevalência de notificações no Brasil. A maior parte das empresas notificantes foram estabelecimentos de saúde, valendo destacar que a maior prevalência de eventos de saúde encontrados para este produto foram EA relacionados a problemas que afetavam o usuário nas tiras de fixação e clipe nasal dos produtos (como desprendimento do clipe nasal e rompimento das tiras de fixação durante o uso) indicando graves indícios de problemas de biossegurança em sua utilização. **Conclusões:** A pesquisa caracterizou os EA e as QT de máscaras com enfoque na promoção da saúde, indicando a necessidade da implantação do monitoramento sanitário dos produtos.

PALAVRAS-CHAVE: Máscaras; Eventos Adversos; Vigilância Sanitária de Produtos; Pandemia

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INTRODUCTION

Health products (HP), hereinafter referred to as correlates, can be defined according to the Brazilian National Health Surveillance Agency (Anvisa) as: equipment, apparatus, material, article, or system for medical, dental, or laboratory use or application, intended for prevention, diagnosis, treatment, rehabilitation, or contraception and that does not use pharmacological, immunological, or metabolic means to perform its main function in human beings, however, it can be helped in its functions by such means[1].

Within this class of products are face protection masks, used as personal protective equipment (PPE). These products can be divided into masks for non-professional use, surgical masks, and respiratory protection masks (respirators)[2,3,4,5]. Of these, the respirators, called N95 masks and filtering half facepiece for particles 2 (PFF2)[3], are half facepieces made up partially or completely of filtering material, which cover the nose, mouth and chin[6].

Although the preventive power of this equipment against infectious agents was already known[7,8,9], masks played a leading role in preventive measures against the new coronavirus pandemic, due to the high transmissibility rate of the SARS-CoV-2 virus that occurs by aerosols from patients with the disease when in contact with the oronasal region of healthy people[10].

Faced with the spread of the disease, the Ministry of Health recommended several clinical protocols and legislation with information on the prevention and therapeutic management of infected patients[11,12]. In addition, several publications have relied on masks as protagonists in the fight against the spread of the disease[13]. In this context, the use of cloth masks with sanitary inspection and cautiously (due to protection limitations) was recommended for places where resources are lacking; use of surgical masks for health workers and other people who have access to environments with other individuals; and masks of type N95, PFF2, or equivalent for environments with wide viral circulation[14]. It is worth mentioning that this guidance provided was provisional and one should always obtain the most up-to-date guidance from competent institutions, such as the Pan American Health Organization (PAHO) due to the dynamics of the findings on the subject.

Regarding the superseded scenario, there was a sanitary concern of the regulation, initially provisionally, about the manufacture, import and commercialization of PPE classified as priority for use in health[15]. Among the groups included in the legislation, masks are foreseen, making strict quality control of products manufactured as they are currently marketed, providing legislative guidance for those who wish to adapt. However, even given the importance and criticality of this equipment, only PFF respirators and masks have legislation that requires mandatory product notification, according to Ordinance No. 561, of December 23, 2014[16].

Regarding mask regulations, due to the characteristics of the pandemic period, some legislation that regulates its manufacturing process gained prominence, becoming a source of reference for product manufacturers[17]. Furthermore, in the national territory it is regulated in the post-marketing and techno-surveillance scenario characteristic of imported products[18,19], and in this scenario, there is a leading role in the inspection of masks that can be reused[20,21,22,23].

As a way to support Anvisa's decision-making on the quality of products, in 2006 a computerized system called Notivisa was created. This platform aims to capture and manage data from adverse event (AE) notifications and technical complaints (TC) of these products[24].

Notivisa, implemented as the official post-use/post-marketing surveillance information system (Vigipós) in Brazil[25], allows any citizen or legal entity to make notifications in the system. For such purposes, AEs are considered to be the possible unwanted complications resulting from the care provided to patients not attributed to the natural evolution of the underlying disease[26]. On the other hand, any notification of suspected alteration or irregularity of a product or company is characterized as TC, in relation to technical or legal aspects, which may or may not cause damage to individual or collective health[24].

Thus, the present work aimed to categorize, quantify, analyze, and evaluate notifications in the Notivisa system between 2010 and 2020 about respirators and surgical masks.

METHOD

This is a cross-sectional, descriptive, retrospective, documentary study with a quantitative approach. Data from Notivisa, sorted from January 2010 to April 2020, were requested from the Drug Surveillance Directorate (DVMC) of the State Health Surveillance of Minas Gerais, which were sent electronically. The search was carried out on all notifications of medical-hospital articles from all states of the Brazilian territory that contained in the search category "Commercial name of the product" the words: surgical masks, filtering half facepiece, disposable mask, or mask. The data collection covered all notifications, regardless of the completion status of investigations written in the system. As a criterion for the inclusion of the work, the notifications should refer to surgical masks or the filtering half facepiece.

After excluding notifications that were not the object of interest of the study, the database was submitted to four stages of analysis by the authors, starting with the verification of whether the notifications made as AE and TC were in accordance with the classification of the Technovigilance Manual from Anvisa. For the analysis and interpretation of the data available in Notivisa, the description of the reported situation was removed from the field "Detailed description of the reason

for the notification (DMOTIVE)" comparing the convergence of the reported data with the indicated classification of the notification as AE or TC.

For this process, AEs were considered as an unwanted effect on humans, resulting from the use of products under sanitary surveillance, and TC as a suspected alteration or irregularity of a product related to technical or legal aspects, and that may or may not cause harm to individual and collective health[24]. In divergent classifications, notifications were reclassified before data tabulation. In this way, the notifications that explicitly informed the contact with the user (such as detachment of the nose clip during use, breaking of the fixation strips reaching the user, and fragility of the material due to the rupture of the tissue), implicitly demonstrating the need to use them for their discovery, they were classified as AE. In contrast to this, notifications of non-conformities in the manufacturing process (such as the presence of insects, mold, broken masks in the box, absence of fixation strips or nose clip perceived before use, and labeling problems) were directed to the TC group.

In the second stage, AE and TC were tabulated in a descriptive way and quantified using Excel® software, using the year and place of occurrence of notifications as analysis variables. Each notification was categorized according to the information available in the system, according to the ABNT NBR 15052 classifications, in the aspects of quality of the material used in the product, composition and manufacture of masks, packaging, and irritability to use. In the third moment, each category was subsegmented by grouping similar notifications for better elucidation of the information.

Finally, the profile of the notifying and notified companies was evaluated. A code was provided for each company in order to ensure the institutions' privacy. Companies were quantified according to the type of establishment (health establishment, other establishments, or not informed), origin of the purchased product (distributors, health establishments, others, or not informed), nationality of the institutions (national or international), and the notified products (surgical masks or respirators).

RESULTS

Between January 2010 and May 2020, 482 notifications were found. Of these, 39 (8%) were excluded for not meeting the inclusion criteria. Within the 443 notifications included, 519 complaints were found. Regarding the notifications, 368 (83%) referred to the surgical mask and 75 (17%) to respirators. Regarding the initial classification of notifications, 425 (96%) were classified as TC and 18 (4%) as AE.

After reclassification of notifications, according to Anvisa's Technovigilance Manual, 343 (77%) were classified as AE, 91 (21%) as TC, and nine (2%) had more than one notification and contained both AE and TC. Thus, 324 (73%) of the notifications had been misclassified.

Of the notifying companies, 427 (96%) were health establishments and 16 (4%) did not inform the profile of their activity. Regarding the acquisition of products, 237 (53%) were acquired from distributors and 206 (47%) from other sources. In addition, of the companies reported, 319 (72%) were mask manufacturers, 46 (10%) importers of the product, and 78 (18%) did not contain this information. Furthermore, most institutions that use the Notivisa system are members of the Sentinel Network, which already have structured Risk Management teams.

Among the notifications evaluated, 40 companies were identified in the notifications. Of these, a single company called "F1" was responsible for 106 (24%) notifications, and when adding the five companies with the highest number of notifications, there is a total of 248 (56%) complaints.

Of the 27 federative units in Brazil, only three did not make any notification, namely: Acre, Amapá, and Roraima. The five states with the highest number of notifications were: São Paulo, 157 (35%); Ceará, 63 (14%); Rio de Janeiro, 44 (10%); Paraíba, 32 (7%); and Paraná, 27 (6%). Thus, the Southeast region of Brazil was the one with the highest number of notifications in Notivisa, accounting for 222 (50%) notifications. The other notifications were distributed in the other regions of Brazil as follows: 127 (29%) in the Northeast; 49 (11%) in the South; 28 (6%) in the North; and 17 (4%) in the Midwest.

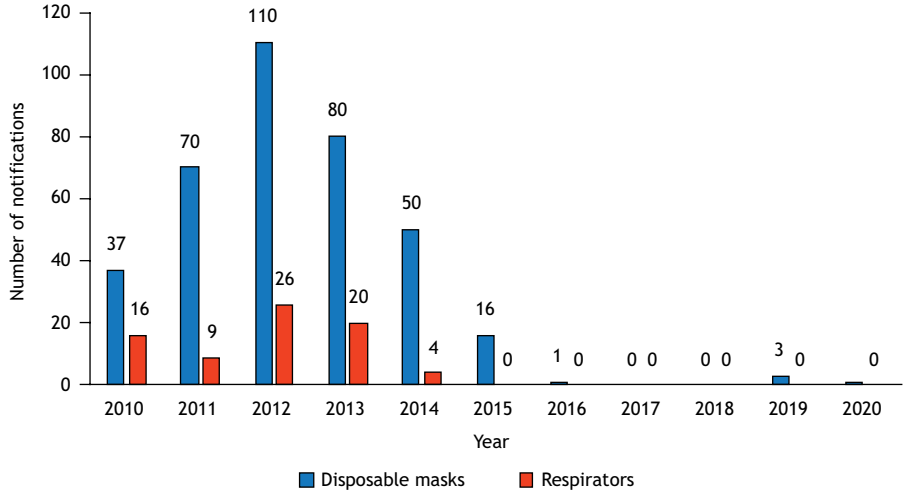
The profile of the number of notifications made according to the year of occurrence was traced. Figure 1 demonstrates the distribution of notifications for disposable masks and respirators over ten years.

The AE categorizations of surgical masks and respirators can be seen in Table 1. In this group were included the notifications that had as scope issues such as: rupture of mask elements with facial injury to the user, discomfort with its use, such as poorly anatomical shapes, and use of equipment with defective filtering element equipment.

Among the notifications, 410 AEs were found, of which 337 (82%) referred to notifications of surgical masks and 73 (18%) of respirators.

Regarding surgical masks, the category with the highest occurrence was "Nose clip", representing 115 (34%) of the notifications. The high rate of appearance of nose clips that come off the mask and hurt the user's face and clips without "memory effect" stands out, preventing the adjustment made to the nose from remaining during medical procedures.

Regarding the TC of the products, the data are shown in Table 2. In order to be included within the group, the notifications referred to the product prior to its use, such as the perception of rupture of the mask structure, presence in the equipment or in its packaging of a foreign body, or uncharacteristic odor, such as assembly defects.



Source: Elaborated by the authors, 2021.

Figure 1. Distribution of notifications of data on surgical masks and respirators between the years 2010 and 2020.

Table 1. Categorization of adverse events (AE) of surgical masks and respirators.

Notification	Surgical masks		Respirators	
	N	%	N	%
Material				
Quality	19	6	0	0
Break	45	13	7	10
Strong odor	9	3	1	1
Nose clip				
Detachment	101	31	6	8
Not malleable	12	4	1	1
Absent	1	0	0	0
Narrow	1	0	0	0
Build				
Filter element	7	2	0	0
Incorrect pressing	1	0	0	0
Shape	7	2	2	3
Fixation				
Strip size	8	2	1	1
Break	98	29	51	70
Bothers	5	1	0	0
Dermal irritability				
Allergy	20	7	3	4
Not specified	3	1	1	1

Source: Elaborated by the authors, 2021.

Among the notifications, 109 TC were identified, being 96 (88%) of surgical masks and 13 (12%) of respirators. It is noted that the number of TC notifications is much lower than that of AE.

DISCUSSION

When it comes to techno-surveillance, AE stands out, which are problems of an international order and represent one of the

Table 2. Categorization of technical complaints (TC) of surgical masks and respirators.

Notification	Surgical masks		Respirators	
	N	%	N	%
Materials				
Quality	0	0	1	8
Break	2	2	1	8
Strong odor	1	1	0	0
Nose clip				
Loose in packaging	7	7	0	0
Absent	7	7	0	0
Build				
Masks sealed together	2	2	0	0
Package				
Packaging	6	6	0	0
Label with lack of information	8	8	1	8
Number lower than the package	4	4	0	0
Fixation				
Absence of straps or loose straps	34	36	3	23
Break	4	4	1	8
Sanitary				
Presence of a foreign body	17	19	2	15
Label	1	1	2	15
Expired registration	2	2	0	0
Not specified	1	1	2	15

Source: Elaborated by the authors, 2021.

major problems in the health area[27,28]. In 2020, specifically, the quality of masks became one of the main issues of collective health due to the coronavirus pandemic, even causing Anvisa to modify the standards and requirements for the manufacture of masks for non-professional use[4].

The discrepancy of the AE number of the initial classification, after its verification with the definitions of the Technovigilance Manual[24], is reinforced by the literature[28]. In addition, there is a low professional qualification for the classification of non-conformities in relation to the product, since mostly, in the descriptions of the notifications, there was clear evidence of the classification of the event that occurred.

Furthermore, the error in this process may be accentuated, since notifications of surgical masks, as they are strictly voluntary, may present a high character of underreporting, as occurs, on a recurring basis, with other related products[25,29,33]. Thus, the interpretation of the data may be biased.

Considering the possibility of resolution by structured risk management teams, the data may not be represented in a totalitarian way[29,31]. It is explained that, in addition to the factors that generate the aforementioned underreporting, another perspective that corroborates this scenario in the survey of the analyzed notifications is the possibility of resolution by the state or municipal Health Surveillance, without the inclusion of data in the Notivisa system[32].

Concisely, the literature portrays the prevalence of notifications in the state of São Paulo, compared to other regions of the country[26,33]. Thus, it is not possible to assess whether the state has a record of reporting due to the high number of occurrences or whether the reporting culture is better consolidated in its institutions.

Regarding the distribution profile of notifications according to the year, there is a drastic reduction for both masks in the studied period, with the data obtained. The difficulty of notifying HP is present in the literature, however, for masks, it occurred more abruptly when compared to other products, reinforcing the importance of users' awareness of its importance and the need to carry out notifications of their nonconformities[25]. It is noticed that this reduction of notification is

characteristic in the notification system and can be linked to the reduction of culture and little professional validation of the importance of its accomplishment[25,27,30].

A factor that may have influenced the quality of the products, and which reflects on the distribution profile of notifications as a function of time, was the publication of Ordinance No. 561 of the National Institute of Metrology, Standardization and Industrial Quality (Inmetro), in December 2014, which established the need for mandatory certification of respirator-type masks. However, the literature reports that the implementation of certification did not significantly interfere in the number of notifications of other related products, such as hypodermic syringes[30]. Furthermore, this regulation would not justify reducing notifications for surgical masks.

In addition, the discrepancy in the notification number of surgical masks and respirators demonstrates that, with regard to this second group, there is already a concern on the part of manufacturers concerning the quality of the product offered for sale. Probably, this attention is due to the nature of use of this equipment, which are often in more adverse situations.

This concern leads to scenarios of highly transmissible infections by droplets, as in the case of the SARS-CoV-2 virus. When the professional is dressed, they are faced with situations in which they feel safe to use the PPE, however, its incorrect use (caused by the user's lack of knowledge of use or poor quality of the product) becomes conducive to the dissemination of several illnesses.

Although the risks related to the user's integrity during the use of PPE are alarming, the difficulty in adapting the nose clip (indicated in the AE) is highly critical when it comes to biosafety issues. With the non-adaptability of the clip, or its absence, the upper region of the orofacial part is unprotected, allowing greater contamination in activities of a medical-hospital nature. Another difficulty of the lack of malleability of the nose clip is the discomfort during work procedures. This factor is recurrent in the classification of "fixation" which holds 111 (33%) of notifications.

Within the "mask support" category, problems with the breakage of the fastening straps accounted for 29% of the notifications. Of these, the reports mostly address the breakage of the strips during the use of the equipment. When the break occurs, it causes injuries to the handler's face and interferes again with the biosafety factor. In addition, the loss of equipment, with the need to change the mask, results in expenses on the part of the institution, also becoming a financial problem.

The third most cited category was "Materials", which contained 73 (22%) notifications of surgical masks. Considering the class of equipment manufacturing material, the break represented 45 (13%) notifications. This data indicates the low quality of the products' manufacturing materials, corroborating the biosecurity concern, since the breakdown of the equipment as a whole exposes the user to the pathogenic agent.

Regarding respirators, the majority category of notifications was "Fixation", with 52 (72%) complaints. The content of these was similar to that of surgical masks, however, it raises alarm again for biosafety issues due to the criticality of the environments where this type of mask is required.

When observing the TC, it appears that, in the classification of surgical masks, the group with the highest prevalence with 38 (40%) occurrences was the "Fixation" category. In the subcategory of "Rupture" in the TC classifications, notifications were included in which the strips, although stuck, were close to breaking in the product box, making it impossible to use the equipment from the beginning.

Within this classification, most of the notifications referred to products that had missing or detached fastening strips inside the box. When finding a batch with this TC, there is imminent adversity at times when the product needs to be used quickly, such as in urgent and emergency environments in hospitals. TC problems with the nose clip also occurred, reinforcing the problem of user exposure.

The second largest class of TC, which accounted for 20 (22%) notifications of surgical masks, is health issues. The "Presence of a foreign body" in the product prevails with 17 (19%) notifications. This topic demonstrates problems during the manufacture of products in relation to Good Manufacturing Practices (GMP). Due to the impossibility of user perception, Notivisa does not cover notifications as microbiological parameters, but this category opens precedents for possible further research.

Product labeling also proved to be a parameter that must be carefully evaluated. Considering that the label problems encompassed issues such as the absence of the Certificate of Approval or the incorrectly typed number of masks, possibly many users do not pay attention to this data, indicating the possibility that this problem is recurrent, although not reported.

Regarding respirator-type masks, the most present TC classes in the database studied were those related to mask attachment, containing four (31%) notifications, and health issues, with four (30%) notifications. It should be noted that there are quality control tests, recommended by regulatory standards, which are not perceived by the user without laboratory tests, making possible parameters of non-compliance of the products difficult to be reported by users. Among such tests, we can mention the determination of particle filtration efficiency and the determination of bacterial filtration efficiency[5].

This reinforces the need for post-marketing monitoring for a more concise investigation of the product. With this action implemented, through the correct sample collection with the detection of the analyzed fiscal parameters, in addition to having

a decrease in problems related to underreporting, greater health promotion will be able to be disseminated.

CONCLUSIONS

Although there is a possibility that the study was not able to cover all AEs and TCs for surgical masks and/or respirators, due to underreporting that are recurrent in related products, the seriousness of the problems surrounding these products was clear, which can cause material, physical damage to the user and economic damage to the institutions that use them. However, there is a need to maintain policies that encourage health professionals to use the Notivisa system.

In addition, the study demonstrated the lack of knowledge of users of the Notivisa system regarding the classification of Anvisa's Technovigilance Manual. Thus, the HP techno-surveillance process proves to be extremely important, in order to ascertain the real AE and TC profile of surgical masks and respirators, as demonstrated by the study.

Future investigative studies would enrich the diagnosis of the decrease in notifications over the years. However, the findings of the study corroborate the need to reinforce the awareness of the professional class about the risks inherent in the use of PPE, especially regarding biosafety parameters.

With the database, it was found that, for surgical masks and respirators, the highest prevalence of occurrence is AE, which, in addition to being international events, directly impact public health. In addition, the parameters of "Fixation" and "Nose clip" of the products were the ones with the highest occurrence of notifications.

It is important to note that compulsory metrology certification can be used as an evaluation resource, but it could not replace monitoring parameters and GMP. Furthermore, the need for surveillance services in the post-marketing period of products was demonstrated[28]. In this way, the need for more careful investigations of the product in the post-market commercialization period is highlighted.

It is noteworthy that the absence of mandatory notification by professionals or health establishments, public or private, demonstrates the fragility of the health surveillance system in the control of these products34. Therefore, the registration of TC and AE and more careful investigations of the products in the post-market period become important tools for the performance of the Health Surveillance bodies, helping to protect the health of the population, and also for the manufacturer itself in taking corrective actions and preparing safer HPs.

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Author's Contributions

Matos RC, Silveira AMM – Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. Nunes AZ, Silva EA, Dias EC, Dutra RS - Acquisition, analysis, data interpretation, and writing of the work. All authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.

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