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# Adverse Events and Technical Complaints of Technologies for the Management of Elimination Ostomies in Brazil

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## ABSTRACT

**Objective:** To describe adverse events and technical complaints involving technologies for the management of elimination ostomies reported in Brazil. **Method:** This cross-sectional descriptive study used secondary data recorded in the Notivisa system. The data encompass adverse events and technical complaints reported from January 2007 to August 2023. Descriptive statistical tools were used for the analysis. **Results:** A total of 2,812 notifications were identified, of which 101 (3.6%) were adverse events, and 2,711 (96.4%) were technical complaints. The state of São Paulo accounted for 884 (31.4%) notifications. Collection bags were the most frequently reported products, with 2,688 (95.6%) notifications, including 84 (3.1%) adverse events and 2,604 (96.9%) technical complaints. Regarding outcomes, 2,718 (96.7%) notifications lacked information, 19 (0.67%) reported urinary retention, 13 (0.46%) reported dermatitis, and 9 (0.32%) reported skin injury. **Conclusion:** The number of notifications has continued to rise in recent years; however, the quality remains low, as evidenced by the high rate of omitted information. Technical complaints about collection bags represent the largest number of notifications in Brazil. The description of outcomes in the use of products for ostomy management is unclear and may lead to the underreporting of significant adverse events such as dermatitis.

DESCRIPTORS: Adverse events, Ostomy, Enterostomal therapy, Patient safety, Medical device safety.

# Eventos adversos e queixas técnicas de tecnologias para o manejo de estomias de eliminação no Brasil

## RESUMO

**Objetivo:** Descrever os eventos adversos e as queixas técnicas de tecnologias para o manejo de estomias de eliminação notificados no Brasil. **Método:** Estudo transversal, descritivo, realizado por meio de dados secundários registrados no Notivisa. Os dados representam eventos adversos e queixas técnicas notificados no período de janeiro de 2007 a agosto de 2023. Para análise, utilizaram-se recursos da estatística descritiva. **Resultados:** Identificaram-se 2.812 notificações, das quais 101 (3,6%) eram eventos adversos e 2.711 (96,4%) queixas técnicas. O estado de São Paulo foi responsável por 884 (31,4%) notificações. As bolsas coletoras foram os produtos mais notificados, apresentando 2.688 (95,6%) notificações, sendo 84 (3,1%) eventos adversos e 2.604 (96,9%) queixas técnicas. Sobre os desfechos, verificou-se a ausência de informações em 2.718 (96,7%) notificações, 19 (0,67%) notificações de retenção urinária, 13 (0,46%) de dermatite e 9 (0,32%) de lesão cutânea.

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**Conclusão:** O número de notificações permanece em ascendência nos últimos anos; entretanto, a qualidade ainda é baixa, representada por alta taxa de omissão de informações. As queixas técnicas de bolsas coletoras representam maior número de notificações no Brasil. A descrição dos desfechos na utilização de produtos para manejo de estomias não é clara e pode gerar subnotificação de eventos adversos importantes, como a dermatite.

DESCRITORES: Eventos adversos. Estomia. Estomaterapia. Segurança do paciente. Segurança de dispositivos médicos.

## Eventos adversos y quejas técnicas de tecnologías para el manejo de ostomías de eliminación en Brasil

RESUMEN

**Objetivo:** Describir los eventos adversos y las quejas técnicas relacionadas con tecnologías para el manejo de ostomías de eliminación reportadas en Brasil. **Método:** Estudio descriptivo y transversal realizado con datos secundarios registrados en Notivisa. Los datos representan eventos adversos y quejas técnicas reportadas desde enero de 2007 hasta agosto de 2023. Se utilizaron recursos de estadística descriptiva para el análisis. **Resultados:** Se identificaron un total de 2.812 notificaciones, de las cuales 101 (3,6%) fueron eventos adversos y 2.711 (96,4%) quejas técnicas. El estado de São Paulo representó 884 (31,4%) de las notificaciones. Las bolsas recolectoras fueron los productos más reportados, con 2.688 (95,6%) notificaciones, incluyendo 84 (3,1%) eventos adversos y 2.604 (96,9%) quejas técnicas. En cuanto a los resultados, hubo falta de información en 2.718 (96,7%) de las notificaciones, retención urinaria en 19 (0,67%), dermatitis en 13 (0,46%) y lesiones cutáneas en 9 (0,32%). **Conclusión:** El número de notificaciones ha seguido aumentando en los últimos años, pero la calidad sigue siendo baja, representada por un alto índice de información omitida. Las quejas técnicas sobre las bolsas recolectoras representan el mayor número de notificaciones en Brasil. La descripción de los resultados en el uso de productos para el tratamiento de las ostomías no es clara y puede llevar a un subregistro de eventos adversos importantes, como la dermatitis.

DESCRIPTORES: Eventos adversos. Estomía. Estomaterapia. Seguridad del paciente. Seguridad de dispositivos médicos.

# INTRODUCTION

Technological advances have grown significantly in the healthcare sector, improving health care and establishing a link between scientific knowledge and the quality of care provision[1]. These advances have directly influenced the safety of care, which remains a challenge in Brazil and worldwide[2,3]. Consequently, discussions have been promoted in various public and private settings, making it a priority for the World Health Organization (WHO) in all its spheres, representing a global concern that directly affects the quality of health services provided[4].

In Brazil, with the establishment of the National Patient Safety Program (PNSP), careful goals were agreed upon for identifying and preventing potential problems and risks posed to patients, mainly with the use of light, light-hard, or hard health technologies[5] through technovigilance actions[6].

Technovigilance is a crucial component of the health system, responsible for monitoring and controlling health technologies. By collecting and analyzing data on reported adverse events and technical complaints[7], it contributes to preventing adverse events and improving the quality of patient care.

In Brazil, reporting of adverse events (harm to the patient) and technical complaints (undesirable outcomes related to products) is mandatory. This process is carried out through the Notification System for Health Surveillance (Notivisa), which aggregates the data into a publicly accessible database[7].

In the context of safe care, certain conditions stand out due to the need for technological resources, among which the care for people with elimination ostomies (urinary or intestinal) is emphasized. This care requires equipment for collecting intestinal effluent and urine, as well as adjuncts for managing complications in the ostomy and peristomal skin[8,9].

Although it is a life-saving surgical procedure, about 80% of these individuals experience complications in the ostomy or peristomal skin. Part of these problems is related to the inadequate use of technologies[10]. Thus, identifying adverse events and technical complaints regarding technologies for managing elimination ostomies can contribute to identifying risks and strategic planning for damage prevention, besides fostering technical and care discussions on the quality of health technologies used in the care of this clientele.

Despite the relevance of the topic, no studies were found that addressed adverse events and technical complaints regarding technologies for managing ostomies. Moreover, it is noted that in Brazil, notification data are aggregated and confined to an information system, which requires the application of filters to retrieve information[7]. This procedure hinders the translation of knowledge into clinical and managerial practice, as well as the proposal of improvements to the technologies by health professionals who provide care to people with ostomies.

Given the above, the following guiding question was formulated: What adverse events and technical complaints related to technologies for managing elimination ostomies were reported in Brazil? The objective of this study is to describe the adverse events and technical complaints related to these technologies as reported in Brazil.

## METHOD

This cross-sectional descriptive study used secondary data recorded in the Notivisa database. The data obtained cover the period from August 2007 to August 2023 and were extracted from the technovigilance subsystem available through the link: https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos/informacoes-analiticas/tecnovigilancia/notificacoes-tecnovigilancia. This subsystem is responsible for receiving and reporting adverse events and technical complaints to adopt measures ensuring the protection and promotion of public health[7].

Preliminarily, information on technical complaints and reported adverse events was filtered using the "product reason" filter, where we opted to search for medical-hospital articles and equipment. Events related to diagnostic reagent kits were excluded as they were unrelated to the study's focus.

From the initial search, 999 families of health articles and equipment were identified. Subsequently, three nurses independently evaluated these groups of articles and selected technologies for managing elimination ostomies based on the technical names registered in Notivisa.

The study variables were: total number of adverse event notifications in Brazil, notifications of adverse events involving each ostomy technology in Brazil, notifications of technical complaints involving each ostomy technology in Brazil, and notifications by risk class.

In this study, definitions from the National Health Surveillance Agency (Anvisa) were adopted and adapted to the study's focus. An adverse event involving elimination ostomy technologies refers to cases where the patient or user suffers harm after using health products such as collection and adjunct equipment. A technical complaint refers to a suspected alteration or irregularity in any item, which may relate to physical or legal aspects and not necessarily cause harm to individual or collective health[7].

The data were entered into Microsoft Excel 2016 and subsequently imported and analyzed using Jasp software version 3.0.1. Descriptive statistical tools (means, frequencies, and percentages) were used for data analysis. The data obtained are secondary from an open-access public information system, which excludes the need for ethical review in accordance with Resolution Nº 466/2012 of the National Health Council (CNS).

## RESULTS

A total of 2,812 notifications related to products for managing elimination ostomies were identified from August 2007 to August 2023. The year 2019 had the highest number of notifications for adverse events and technical complaints, as described in Table 1.

The annual frequency of notifications varied throughout the years. However, as demonstrated in Figure 1, it was consistently higher each year compared to 2007.

Regarding notifications by state, the highest number of adverse events and technical complaints were reported in the state of São Paulo, accounting for 884 (31.4%) notifications. Conversely, Roraima and Rondônia had the lowest number

**Table 1.** Notifications of Adverse Events and Technical Complaints Related to Ostomy (2007-2023) – Brazil, 2023

| Year | Notifications | % | Adverse Event | % | Technical Complaint | % |
|---|---|---|---|---|---|---|
| 2007 | 82 | 2.92 | 8 | 7.92 | 74 | 2.73 |
| 2008 | 99 | 3.52 | 5 | 4.95 | 94 | 3.47 |
| 2009 | 113 | 4.02 | 2 | 1.98 | 111 | 4.09 |
| 2010 | 103 | 3.66 | 2 | 1.98 | 101 | 3.73 |
| 2011 | 92 | 3.27 | 9 | 8.91 | 83 | 3.06 |
| 2012 | 144 | 5.12 | 2 | 1.98 | 142 | 5.24 |
| 2013 | 163 | 5.80 | 1 | 0.99 | 162 | 5.98 |
| 2014 | 124 | 4.41 | 2 | 1.98 | 122 | 4.50 |
| 2015 | 208 | 7.40 | 4 | 3.96 | 204 | 7.52 |
| 2016 | 129 | 4.59 | 2 | 1.98 | 127 | 4.68 |
| 2017 | 148 | 5.26 | 3 | 2.97 | 145 | 5.35 |
| 2018 | 149 | 5.30 | 6 | 5.94 | 143 | 5.27 |
| 2019 | 288 | 10.24 | 14 | 13.86 | 274 | 10.11 |
| 2020 | 234 | 8.32 | 4 | 3.96 | 230 | 8.48 |
| 2021 | 234 | 8.32 | 9 | 8.91 | 225 | 8.30 |
| 2022 | 248 | 8.82 | 18 | 17.82 | 230 | 8.48 |
| 2023 | 254 | 9.03 | 10 | 9.90 | 244 | 9.00 |

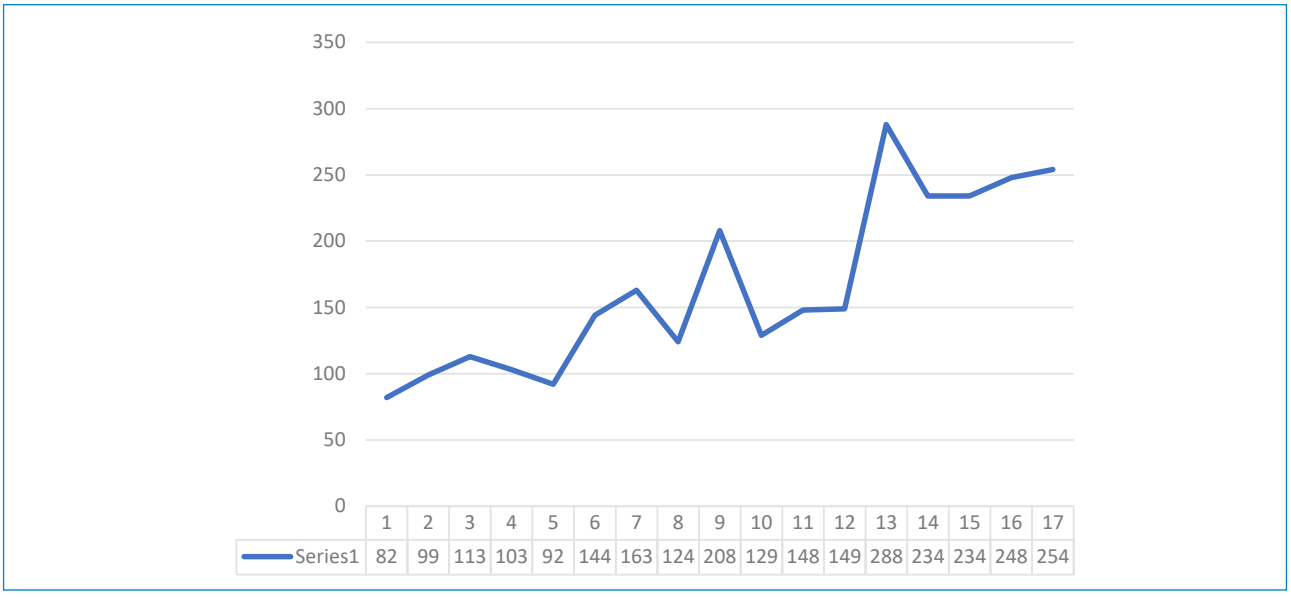


**Figure 1.** Evolution of notifications (2007–2023) – Brazil, 2023.

of notifications during the analysis period, with only two (0.07%) notifications. Additionally, 115 (4.1%) notifications were not linked to any state.

Collection bags were the most frequently notified products for ostomy management. The stoma protector had the lowest frequency of notifications, with only one technical complaint and no adverse events, as shown in Table 2.

Concerning the risk of reported events, 921 (32.75%) were classified as level I, 1,889 (67.18%) as level II, and two (0.07%) as level III. Regarding adverse events following the use of products for managing intestinal elimination ostomies, it was found that 2,718 (96.7%) notifications lacked information for classifying the occurrence and identifying the adverse event or technical complaint. Urinary retention was the most frequently reported event, accounting for 19 (0.67%) events, as shown in Table 3.

**Table 2.** Technologies for Ostomy Management Reported – Brazil, 2023

| Technical Name | Total | % | Adverse Event | % | Technical Complaint | % |
|---|---|---|---|---|---|---|
| Collection Bags | 2,688 | 95.59 | 84 | 3.1 | 2,604 | 96.9 |
| Colostomy Bag | 44 | 1.56 | 5 | 11.4 | 39 | 88.6 |
| Ostomy Accessories | 42 | 1.49 | 9 | 21.4 | 33 | 78.6 |
| Protective Paste | 13 | 0.46 | 0 | 0 | 13 | 100 |
| Ostomy Plate | 24 | 0.85 | 3 | 12.5 | 21 | 87.5 |
| Stoma Protector | 1 | 0.05 | 0 | 0 | 1 | 100 |

**Table 3.** Adverse Events after the Use of Ostomy Products Reported – Brazil, 2023

| Event | Total | % |
|---|---|---|
| Not informed | 2,718 | 96.7 |
| Urinary retention | 19 | 0.67 |
| Dermatitis | 13 | 0.46 |
| Skin injury | 9 | 0.32 |
| Infection | 8 | 0.28 |
| Quality issue in health product | 7 | 0.25 |
| Pain | 6 | 0.21 |
| Hyperemia | 4 | 0.14 |
| Leakage | 5 | 0.14 |
| Micturition alteration | 6 | 0.18 |
| Skin irritation | 3 | 0.11 |
| Circumstance likely to cause medication error | 2 | 0.07 |
| Bladder discomfort | 2 | 0.07 |
| Allergy | 1 | 0.04 |
| Increased susceptibility to infections | 1 | 0.04 |
| Discomfort with health product | 1 | 0.04 |
| Involuntary diuresis | 1 | 0.04 |
| Hematuria | 1 | 0.04 |
| Hemothorax | 1 | 0.04 |
| Respiratory failure | 1 | 0.04 |
| Pneumothorax | 1 | 0.04 |
| Fall | 1 | 0.04 |
| Trauma from foreign body | 1 | 0.04 |

As for technical complaints, it was found that most of them—1,611 (59.4%)—lacked information for classification. Leakage was the most frequently classifiable complaint. Additionally, various events with frequencies lower than 1% were aggregated and presented as "others," as shown in Table 4.

## DISCUSSION

The number of notifications for healthcare technologies has grown substantially in recent years[11]. Consequently, it has become necessary to establish a secure system for formalizing these notifications and managing risks[12].

The notification of health products began in 2007 through Notivisa and its technovigilance subsystem[7]. Technovig lance is understood as the area responsible for identifying breakdowns or lack of quality and/or undesirable outcomes of products that affect patient well-being[11,12].

Technovigilance for products aimed at ostomy care has evolved in recent years, following projections of increased notifications[11,12]. This represents significant progress for users' quality of life and rehabilitation, as they have access to effective equipment properly monitored by healthcare professionals[13].

This study found that since the implementation of Notivisa, notifications of adverse events and technical complaints have increased. Several factors may be related to this growth, particularly the enactment of legislation in defense of people with ostomies and the training of specialist professionals.

Ministry of Health Ordinance Nº 400 is an example of legislation contributing to the safety of care for people with ostomies. It establishes National Guidelines for the Health Care of People with Ostomies within the Unified Health System (SUS) and emphasizes the proper use of collection and adjunct equipment, focusing on the safety and protection of people with ostomies[9].

Nonetheless, even with the implementation of public policies, the quality of notifications remains unsatisfactory. There is a lack of essential information for situational analysis and strategic planning, which exposes users of these technologies to the risks of adverse events.

A study conducted by Sousa et al. highlights the main factors influencing the notification of adverse events, including fear of punishment, lack of knowledge, work overload, and lack of professional commitment, leading to underreporting[14]. Difficulties and lack of preparation in using the notification form within institutions were also noted. Some positive aspects highlighted include the support from the Patient Safety Center, feedback on notifications, and recognition of the importance of reporting adverse health events[15].

In this study, 96.7% of notifications lacked relevant information to ensure quality, such as the notifying state, type of event, characteristics and circumstances of the event, and type of product failure. This finding aligns with results from a cross-sectional study that confirmed the low quality and lack of clarity in adverse event and technical complaint notifications[12].

**Table 4.** Technical Complaints of Ostomy Products Reported – Brazil, 2023

| Technical Complaint | Total | % |
|---|---|---|
| Not informed | 1,611 | 59.4 |
| Others | 578 | 21.3 |
| Leakage | 122 | 4.5 |
| Cracking | 121 | 4.5 |
| Material breakage | 91 | 3.4 |
| Material perforation | 63 | 2.3 |
| Degradation | 44 | 1.6 |
| Contaminated during transport | 27 | 1 |
| Failure to adhere or fix | 27 | 1 |
| Burst/Rupture | 27 | 1 |

The absence of information makes it impossible to understand the event's characteristics and consequently implement preventive actions, which protect patients from adverse events and ensure the quality of available equipment on the market.

The state of São Paulo was responsible for the majority of notifications. This state was a pioneer in offering a specialization course in enterostomal therapy, becoming a reference in specialized teaching and research, which contributes to the training of nurses in recognizing technical complaints and adverse events[16].

It is noteworthy that the management of elimination ostomies requires health technologies, especially collection and adjunct equipment[8,9]. The technologies most cited in the literature include collection bags, adhesive bases, belts, skin protectors in ring or paste form, spray and barrier cream, stoma protectors, and colostomy irrigation kits[9,13].

Not all technologies were registered in Notivisa, making it impossible to report adverse events and technical complaints for some technologies. Additionally, technologies were described using outdated and generic technical names, making it difficult to identify their technical specifications clearly. For example, collection bags and colostomy bags, which had the most notifications in this study, lacked sufficient technical specifications to characterize the product, given the variety of products on the market.

The fact that collection bags had the most notifications may be justified by the nature of this technology, which most patients with intestinal and urinary ostomies use[9,13]. Collection bags are used to collect intestinal effluent and urine and come in various sizes, shapes, and compositions[8,13]. Conversely, the stoma protector had few notifications, which is understood as this product is limited to those who perform intestinal irrigation and have specific requirements for its indication[17].

It is important to note that technical complaints were the most frequently reported events, with the primary outcome being leakage of effluent or urine from collection equipment. People with ostomies identify leaks in collection equipment as a priority problem that interferes with quality of life, adaptation, and rehabilitation[18,19].

A study conducted with 54,614 people with ostomies from 17 countries, including Brazil, indicated that 76% of respondents, regardless of the type of stoma, reported experiencing effluent leakage under the adhesive base at least once a month. Additionally, 65% of them experienced effluent leakage outside the base plate and onto clothing at least once in the previous year[20]. This fact contributes to the occurrence of peristomal skin complications[8].

In this study, dermatitis was the most frequently reported adverse event. Dermatitis is a common complication of peristomal skin[8,10]. Factors associated with dermatitis in patients with ostomies are not always directly linked to the stomas and may relate to improper use or handling of collection equipment[21].

Studies reinforce that dermatitis may relate to the lack of preoperative delineation, abuse of equipment and topical products (irritant contact dermatitis), allergic reactions to special materials (allergic dermatitis), mechanical damage caused by excessive hygiene, and operational equipment[22-25]. It may also be related to chemical injury from effluent leakage from the stoma, mucocutaneous separation, and mechanical trauma, as well as adhesive removal injuries due to repeated application of the adhesive base[8,22,23,26].

Thus, it is asserted that choosing the appropriate collection equipment and making the ideal cut is fundamental to avoiding some complications in the peristomal skin[8]. The use of moldable collection equipment resulted in a significantly lower incidence of irritation compared to conventional equipment, besides greater satisfaction among users. It is worth noting that the application of collection equipment with specific compositions can help maintain skin integrity[10].

Another highlight is the use of skin protection products to prevent dermatitis, which, contrary to their indication, may cause skin reactions. In this context, a study evaluated 18 patients identified as having dermatitis, of whom 12 had peristomal contact dermatitis. Various stoma care products were identified as triggers for irritant and/or allergic contact dermatitis. The most commonly involved product in stoma skin dermatitis was Cavilon™ No Sting Barrier Film[27].

Preventive measures, such as using hydrocolloid barriers and cleaning with low-pH detergent and fabric, were effective in preventing dermatitis[8,23]. Additionally, proper care and maintenance of the stoma, including the use of protective film, were crucial in minimizing the risk of stoma-related complications[28]. Therefore, the surveillance of health products by trained professionals who can recommend technologies and recognize adverse events is essential for the safety of healthcare[8].

It is known that dermatitis presents as a significant complication affecting quality of life, causing skin reactions characterized by pain, hyperemia, and increased moisture, resulting in discomfort and poor adhesion of the adhesive base of the

collection equipment[28]. Despite this, in the present study, the reported adverse events were classified as level I risk, which is considered low risk. However, this information raises reflection on the risk classification of health products in Brazil, as the reported products caused urinary retention, dermatitis, skin injury, infection, and pain, among others, most of which require interventions, contradicting the precepts of level I risk events[7,11].

It is worth noting that the classification of events is generic and does not ensure that the aggregation of events was done correctly, as some signs and symptoms of dermatitis are classified into one category, which may lead to incorrect inferences.

Thus, a limitation of the study is the difficulty in accurately identifying the technical specifications of the product to relate the reported product to the adverse event or technical complaint. An example of this is collection bags, which can be used in urinary ostomies but also attached to catheters.

Another point to consider is that the classification of events does not provide sufficient details to understand the event and its circumstances, which may hinder the identification of important events, such as dermatitis (when reporting signs and symptoms), and influence its prevalence.

## CONCLUSION

This study identified 2,812 notifications of adverse events or technical complaints. The majority of notifications lacked relevant information to understand the events and propose preventive measures. Additionally, most products were classified as low risk; however, the notifications indicate adverse events that could lead to severe complications.

Given this, the technovigilance subsystem still has flaws in information production, as it does not clearly reproduce adverse events and technical complaints with ostomy products in Brazil. Therefore, it is necessary to train healthcare professionals to identify the technical specifications of ostomy products and diagnose adverse events, ensuring that notifications are carried out completely and provide quality information.

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