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# Study of transfusion reaction rate of health institutions accredited in the Sentinel Network of the Anvisa in 2017

## Estudo da taxa de reação transfusional das instituições de saúde credenciadas à Rede Sentinela da Anvisa, do ano de 2017

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## ABSTRACT

**Introdução:** A hemovigilância é um elemento da segurança de transfusão sanguínea. As informações advindas da Rede Sentinela integraram o Sistema Nacional de Vigilância Sanitária no pós-uso ou pós-comercialização, com a finalidade de subsidiar a vigilância sanitária nas ações de regulação desses produtos no mercado. **Objetivo:** Demonstrar valores da taxa de reação transfusional (RT) que reflitam a situação das instituições que compõe a Rede Sentinela, a partir de dados do monitoramento da Rede, no ano de 2017. **Método:** Foi realizado um estudo retrospectivo, descritivo, com abordagem quantitativa. A amostra de estudo constou de 172 planilhas oriundas dos relatórios enviados por 191 serviços integrantes da Rede Sentinela, com dados referentes ao monitoramento de pelo menos um dos semestres do ano de 2017. **Resultados:** Dos 254 serviços credenciados à Rede Sentinela em 2017, 191 instituições enviaram relatório com dados de pelo menos um dos semestres no período em estudo. Desse total de serviços que enviaram o monitoramento, 183 (95,8%) afirmaram ter realizado transfusões de sangue e 120 (62,8%) instituições enviaram planilhas com taxa de RT do estabelecimento de saúde. A taxa geral de RT identificada entre instituições que compõem a Rede Sentinela, para o ano de 2017, foi de 5,29 RT a cada 1.000 transfusões realizadas. **Conclusões:** A taxa geral de RT identificada foi 5,29 RT a cada 1.000 transfusões. Identificar a taxa de reação transfusional é um passo importante no gerenciamento de risco de uma instituição por possibilitar o desenvolvimento de estratégias de incremento de qualidade no processo transfusional.

**PALAVRAS-CHAVE:** Hemovigilância; Reação Transfusional; Rede Sentinela; Sangue

## RESUMO

**Introduction:** Haemosurveillance is an element for the safety of blood transfusion processes. The information provided by the Sentinel Network integrated the Post-National System of Sanitary Surveillance in registration and Post-Commercialization, with the purpose of subsidizing Sanitary Surveillance in the actions of regulation of these products. **Objective:** Obtain transfusion reaction rate (RT) values that reflect the situation of the institutions that make up the Sentinel Network, based on network monitoring data, in 2017. **Method:** A retrospective cross-sectional, descriptive study with a quantitative approach was performed. The study sample consisted of 172 spreadsheets from reports sent by 191 Sentinel Network member services, with data referring to the monitoring of at least one of the semesters of 2017. **Results:** Of the 254 accredited services in the Sentinel Network in 2017, 191 institutions submitted a report with data from at least one of the semesters during the study period. Of these services, 183 (95.8%) reported having had blood transfusions and 120 (62.8%) institutions sent spreadsheets with RT rates from the health facility. The overall rate of RT identified among institutions that make up the Sentinel Network for 2017 was 5.29 RT per 1,000 transfusions performed. **Conclusions:** The rate of RT identified was 5.29 RT per 1,000 transfusions. Identifying the transfusion reaction rate is an important step in institution's risk management as it enables the development of quality improvement strategies in the transfusion process.

**KEYWORDS:** Haemosurveillance; Transfusion Reaction; Sentinel Network; Blood

## INTRODUCTION

Blood transfusion is a common practice in intensive care. It is not a risk-free activity and is associated with several adverse events like infections, acute lung injury, volume overload, immune changes and hemolytic reactions[1]. In a recent survey on the International Haemovigilance Network Database, which represents 25 countries, scientists found that the adverse reaction rate to blood product transfusions was 660 per 100,000 individuals[2].

In Brazil, the introduction of risk management measures in blood therapy through Ordinance n. 121, of November 24, 1995[3], published by the Ministry of Health to regulate the script for inspection in blood therapy units, represented an important step in the process of minimizing errors, since it establishes basic routines for the various activities done in hemotherapy facilities[4]. According to Carrazzone et al.[5], transfusion safety involves a set of measures to decrease the risks to blood donors and recipients.

Ordinance of the Ministry of Health (MS) n. 1.660, of July 22, 2009, created the Health Surveillance Reporting and Investigation System (Vigipós) under the Brazilian Health Surveillance System (SNVS), part of the Brazilian Unified Health System (SUS). Vigipós is responsible for monitoring, analyzing and investigating adverse events and technical complaints related to the services and products under health surveillance in the post-marketing or post-use phase. As a strategy to implement Vigipós, the Sentinel Network, regulated by Resolution of the Collegiate Board of Directors (RDC) n. 51, of September 25, 2014[6], works as an observer of health risk management services and is made of a set of institutions that work with SNVS entities. Each institution must create a Risk Management, which is the Vigipós' internal reference responsible for reporting adverse events and technical complaints about the products under health surveillance in Brazil. According to Normative Instruction n. 8, of December 19, 2014, risk management activities by the institutions accredited in the Network must be monitored every six months by the Brazilian Health Surveillance Agency (Anvisa) and the collected data must be registered[7].

Haemovigilance is a tool for increasing transfusion safety that consists of an assessment and alert system that monitors the transfusion processes constantly. It is designed with the objective of collecting and assessing information about undesirable and/or unexpected effects following the use of blood components in order to prevent their appearance or recurrence. Haemovigilance is part of the health surveillance actions done in Brazil and represents one of the strategic areas of Anvisa and the Minstry of Health[8].

The transfusion reaction (TR) rate is an important evaluation parameter for regulatory agencies in other countries, like in the Serious Hazards of Transfusions (SHOT) haemovigilance system, that aims at minimizing transfusion errors in the United Kingdom, or the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM), in France, where reporting is mandatory, like in Brazil[9,10]. Despite using references from other international haemovigilance systems[11], Brazil still lacks an adverse reaction rate in haemovigilance, and the French parameter is used, in some occasions, in prospective statistics.

In view of the interest in surveying information for haemovigilance purposes, this study used data of the Sentinel Network monitoring from 2017 to demonstrate TR rate values that shed light on the situation of the institutions that make up the Network. The publication of studies involving a greater number of health institutions throughout the country aims to offer information that can be used to perform actions based on data that shows the Brazilian reality.

## METHODS

We conducted a retrospective, descriptive and quantitative study to identify the TR rate from data collected by the Sentinel Network from January to December 2017. The study sample consisted of 172 spreadsheets from the reports sent by some institutions accredited to the Sentinel Network that filled out at least one standard report in one semester of 2017. The data of the reports were obtained from the Sentinel Network Monitoring Form, a document filled out by the institutions in the FormSus database. The monitoring of 2017 occurred in two stages, by sending two forms, one at each semester.

Every form has 76 items with questions distributed in sections that group questions about risk control, monitoring, communication, minimization, integration with other areas, training and continuing education, Brazilian patient safety program and groups of questions about specific points of monitoring strategies in pharmacovigilance, technosurveillance, haemovigilance and biovigilance. In this study, we analyzed, along with data about the institution identification, like state and Haemovigilance section, specifically, the following items:

- "Did you perform transfusions during the monitored period?";
- "Transfusion Reaction Rate 1st Semester of 2017" and/or "Transfusion Reaction Rate 2nd Semester of 2017".

If the answer to the first question was yes, the institution should attach a spreadsheet, with a previously established design, with data on the evaluated semester. As an inclusion criterion, we considered the spreadsheets with data about haemovigilance monitoring sent by the units belonging to the Sentinel Network through the Sentinel Network Monitoring Form (2017.1) and the Sentinel Network Monitoring Form (2017.2). Therefore, we excluded the institutions that did not send haemovigilance monitoring spreadsheets or that stated that there were no transfusions during the period. The dependent variables were the number of TR cases identified monthly by the institution and the amount transfused. The independent

variable was the TR rate identified at the institution. We present the rates by type of blood component, stratified according to the number of transfusions of the blood component and the amount of TR presented, according to the formula:

Blood component transfusion reaction rate = amount (n) of the blood component transfusion reactions / total (n) of the blood component transfusions

The overall rate was calculated considering the number of TR per number of transfusions in each health institution, according to the following formula:

Transfusion reaction rate (T x TR) = amount (n) of transfusion reactions / total (n) of transfusions

We consolidated the Sentinel Network Monitoring forms of 2017 sent through the FormSus platform. We downloaded the database and stored it in Microsoft Excel version 2016 spreadsheets, which were compatible with the form structure. After the download, we analyzed the data through descriptive statistics. We used techniques of frequency distribution and mean of variables. We showed the results in tables and graphs and discussed them according to the existing literature.

## RESULTS AND DISCUSSION

We considered the consolidated data of the health units (HU) that sent at least one monitoring report performed in 2017. In this year, 254 institutions formed the Sentinel Network and 191 sent at least one semester report. We excluded the 63 institutions that did not send reports in 2017. Therefore, we analyzed 191 institutions of the Sentinel Network based on data from the first and/or second semesters of 2017. Considering all the institutions and the monitored period, 183 (95.8%) HU performed blood transfusions and 8 (4.2%) did not, as shown in Table 1. There is a higher concentration of units in the states of the Southeast and South regions of Brazil, where there are 117 (63.93%) HU.

Among the institutions that performed transfusions, 120 (62.8%) sent at least one spreadsheet with the consolidated data about their TR rates during the first and/or second semester of 2017, as shown in Table 2. The monitoring of 2017 occurred in two

**Table 1.** Number of institutions that performed blood transfusions during the monitored period, by state. Brazil, 2017.

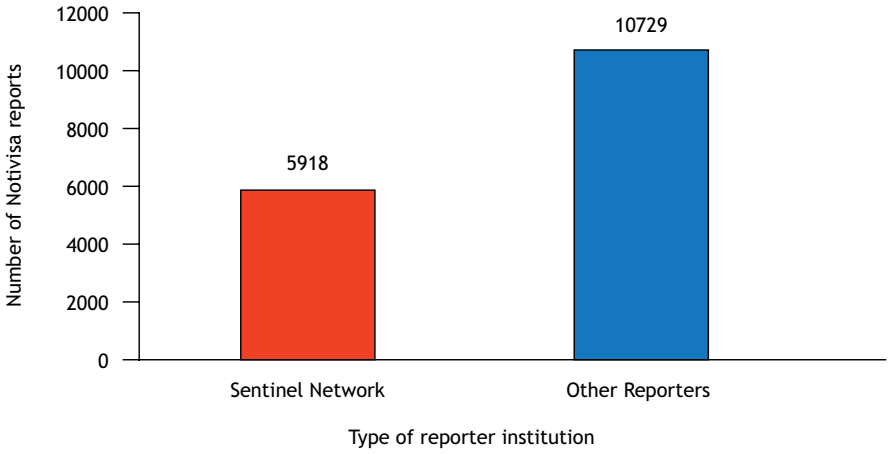
| State | 2017 | |
|---|---|---|
| | N | % |
| Alagoas | 3 | 1.64 |
| Amazonas | 2 | 1.09 |
| Bahia | 5 | 2.73 |
| Ceará | 13 | 7.10 |
| Federal District | 7 | 3.83 |
| Mato Grosso do Sul | 2 | 1.09 |
| Maranhão | 2 | 1.09 |
| Minas Gerais | 19 | 10.38 |
| Pará | 3 | 1.64 |
| Paraíba | 5 | 2.73 |
| Paraná | 10 | 5.46 |
| Pernambuco | 6 | 3.28 |
| Rio de Janeiro | 19 | 10.38 |
| Rio Grande do Norte | 3 | 1.64 |
| Rio Grande do Sul | 11 | 6.01 |
| Rondônia | 4 | 2.19 |
| Santa Catarina | 15 | 8.20 |
| São Paulo | 53 | 28.96 |
| Sergipe | 1 | 0.55 |
| **Total** | **183** | **100** |

*The institution stated that it performed transfusions, but did not send the necessary data for analysis.
Source: Sentinel Network Monitoring Forms of 2017.

**Table 2.** Number of institutions that sent data about its transfusion reaction rate, by state. Brazil, 2017.

| State | 2017 | |
|---|---|---|
| | N | % |
| Alagoas | 2 | 1.67 |
| Amazonas | 2 | 1.67 |
| Bahia | 3 | 2.50 |
| Ceará | 6 | 5.00 |
| Federal District | 3 | 2.50 |
| Mato Grosso do Sul | 2 | 1.67 |
| Maranhão | 2 | 1.67 |
| Minas Gerais | 16 | 13.33 |
| Pará | 2 | 1.67 |
| Paraíba | 4 | 3.33 |
| Paraná | 7 | 5.83 |
| Pernambuco | 4 | 3.33 |
| Rio de Janeiro | 14 | 11.67 |
| Rio Grande do Norte | 3 | 2.50 |
| Rio Grande do Sul | 6 | 5.00 |
| Rondônia | 1 | 0.83 |
| Santa Catarina | 9 | 7.50 |
| São Paulo | 34 | 28.33 |
| Sergipe | 0 | 0.00 |
| **Total** | **120** | **100** |

*The institution stated that it performed transfusions, but did not send the necessary data for analysis.
Source: Sentinel Network Monitoring Forms of 2017.




Source: Notivisa - Anvisa.

**Figure 1.** Number of transfusion reaction reports, according to whether or not the service makes up the Sentinel Network. Brazil, 2017.

steps, by sending two forms, one per semester. However, some institutions sent two reports and others only one, for the first or second semester, which is why the analysis of the TR rate was performed with a sample of 172 spreadsheets. Each spreadsheet consolidated the data about the institution's TR rate in one of the 2017 semesters.

Reports from the Sentinel Network account for an important percentage of the adverse reaction reports involving blood and its components received by Notivisa, as shown in Figure 1, which presents data from the computer system designed by Anvisa to receive incident reports, adverse event reports and technical complaints related to the products and services under health surveillance. The Sentinel Network services are representative among the reports of reactions involving blood and its components, with a percentage of 35.54% of the reports received by the Notivisa system in 2017. It is worth emphasizing that, according to Haemovigilance Bulletin n. 7[11], published by Anvisa in 2015, the institutions that make up the Sentinel Network represent about 3% of all the health facilities that are equipped to perform blood transfusions and that 20% – 30% of them still do not report.

We found a general TR rate value of 5.29 TR per 1,000 transfusions, as shown in Table 3. This value is higher than the reference parameter used in Anvisa haemovigilance reports[11], based on the French haemovigilance system statistics, which present a value of three TR per 1,000 transfused blood components (3 TR/1,000). In a study carried out with data from some Italian health institutions[12], the adverse reaction rate found was 0.8 TR per 1,000 transfused blood components. Harvey et al.[13] analyzed transfusion data from 77 institutions in the United States and found an adverse reaction rate of 2.39 RT/1,000 transfusions. In order to identify data about Brazil, Table 3 also shows the TR rates by state, considering the location of the institutions that provided data. The separation by state is similar to a study performed in Italy[12], however, it is important to mention that the distribution of health institutions by state in the Sentinel Network is variable and there is a higher concentration of health units in the South and Southeast regions, as shown in Table 1. No institution of the states of Goiás, Mato Grosso, Piauí, Acre, Amapá, Roraima, Tocantins and Espírito Santo sent data about their TR rates on the monitoring reports of the Sentinel Network in 2017.

Figure 2 presents the TR rates by type of blood component. It is interesting to notice that, although red blood cells concentrate (RBCC), platelet concentrate (PC) and fresh frozen plasma (FFP) are among the blood components with the highest rates of TR, similar to other studies[14,15,16,17], the reaction rate involving the granulocyte concentrated (GC) we found in this study was significantly high. We did not consider the different types of filtration and/or preparation of the blood component for data analysis.

The number of institutions evaluated is a limitation of this study. This number is considerably lower than the number of institutions that make up the data in the "Information Notebook: Blood and Blood Products"[18]. Also, the non-proportional distribution of institutions among Brazilian states makes it difficult to generalize data at a national level. However, data within the Sentinel Network services are collected through an annual survey performed by unit, under the responsibility of the institution's risk managers, as determined by RDC n. 51/2014, thus presenting greater proximity to the reality of the institutions that are members of the Sentinel Network[6]. Furthermore, the possibility of underreporting, a problem reported in many studies on Haemovigilance[12,14,19], is a recurring issue when trying to estimate TR rates.

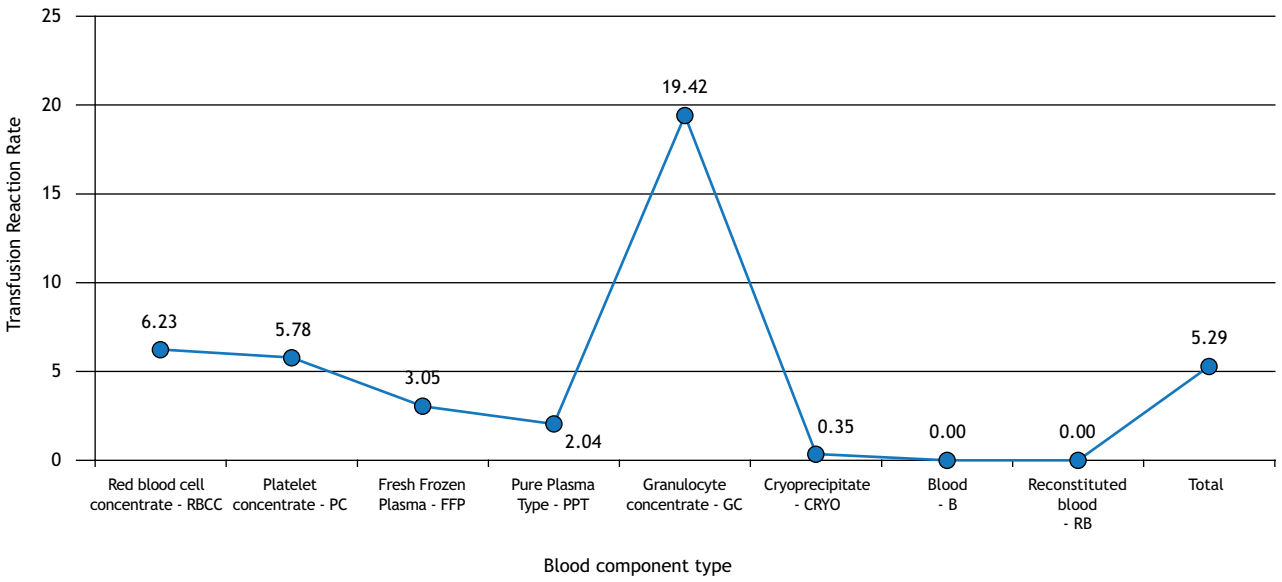
## CONCLUSIONS

The general TR rate we found among institutions that make up the Sentinel Network for the year 2017 was 5.29 TR per 1,000 transfusions. Identifying the RT rate is an important step in an institution's risk management because it enables the design of

**Table 3.** Transfusion reaction rates by state according to the Sentinel Network monitoring of 2017. Brazil, 2017.

| State | Transfusions | Transfusion Reactions | Rate* |
|---|---|---|---|
| Federal District | 5,828 | 27 | 4.63 |
| Mato Grosso do Sul | 10,191 | 20 | 1.96 |
| **Center-West** | **16,019** | **47** | **2.93** |
| Alagoas | 4,289 | 50 | 11.6 |
| Bahia | 11,511 | 99 | 8.60 |
| Ceará | 28,624 | 177 | 6.18 |
| Maranhão | 4,004 | 75 | 18.7 |
| Paraíba | 8,088 | 24 | 2.97 |
| Pernambuco | 20,066 | 82 | 4.09 |
| Rio Grande do Norte | 7,149 | 39 | 5.46 |
| **Northeast** | **83,731** | **546** | **6.52** |
| Amazonas | 5,212 | 16 | 3.07 |
| Pará | 3,756 | 11 | 2.93 |
| Rondônia | 6,568 | 17 | 2.59 |
| **North** | **15,536** | **44** | **2.83** |
| Minas Gerais | 53,991 | 107 | 1.98 |
| Rio de Janeiro | 65,674 | 349 | 5.31 |
| São Paulo | 251,611 | 1,205 | 4.79 |
| **Southeast** | **371,276** | **1,661** | **4.47** |
| Paraná | 43,096 | 260 | 6.03 |
| Rio Grande do Sul | 40,168 | 358 | 8.91 |
| Santa Catarina | 19,804 | 203 | 10.25 |
| **South** | **103,068** | **821** | **7.97** |
| **Brazil** | **589,630** | **3,119** | **5.29** |

*The rate represents the amount of transfusion reactions per 1,000 transfusions, by state
Source: Sentinel Network Monitoring Forms of 2017.




*The rate represents the amount of transfusion reactions involving the blood component per 1,000 blood transfusions.
Source: Sentinel Network Monitoring Forms of 2017.

**Figure 2.** Transfusion reaction rate by type of blood component, per 1,000 transfusions. Brazil, 2017.

strategies to increase the quality of the transfusion process. However, other studies are essential to consolidate a TR rate that reflects the reality of the National Haemovigilance System.

The safety and quality of blood and its components must be guaranteed throughout the process, from the collection of donors to their administration to patients. Encouraging a qualified error reporting culture is fundamental to monitor blood safety and help risk managers make better decisions to identify and solve blood-related problems. We hope that the data we presented can contribute to the improvement of haemovigilance services.

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## Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.