Systematic Review

doi: https://doi.org/10.1590/1983-1447.2024.20230097.en

Prevalence of errors causing events allegedly attributable to vaccination/immunization: systematic review and meta-analysis

Prevalência de erros que causaram eventos supostamente atribuíveis à vacinação/imunização: revisão sistemática e metanálise

Prevalencia de errores causantes de acontecimientos supuestamente atribuibles a la vacunación/inmunización: revisión sistemática y metanálisis

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How to cite this article:
Tavares LOM, Silva MA, Oliveira BR, Amaral GG, Guimarães EAA, Couto RO, Oliveira VC. Prevalence of errors causing events allegedly attributable to vaccination/immunization: systematic review and meta-analysis. Rev Gaúcha Enferm. 2024;45:e20230097. doi: https://doi.org/10.1590/1983-1447.2024.20230097.en

ABSTRACT

Objective: To identify the prevalence of errors that caused events supposedly attributable to vaccination or immunization.

Method: Systematic literature review with meta-analysis carried out on the Medline, Cochrane Library, Cinahl, Web of Science, Lilacs, Scopus; Embase; Open Grey; Google Scholar; and Grey Lit databases; with studies that presented the prevalence of immunization errors that caused events or that provided data that allowed this indicator to be calculated.

Results: We evaluated 11 articles published between 2010 and 2021, indicating a prevalence of 0.044 errors per 10,000 doses administered (n=762; $CI_{95\%}$: 0.026 – 0.075; $I^2 = 99\%$, $p < 0.01$). The prevalence was higher in children under 5 (0.334 / 10,000 doses; n=14). The predominant events were fever, local pain, edema and redness.

Conclusion: A low prevalence of errors causing events was identified. However, events supposedly attributable to vaccination or immunization can contribute to vaccine hesitancy and, consequently, have an impact on vaccination coverage.

Descriptors: Immunization. Vaccination. Medication errors. Systematic review.

RESUMO

Objetivo: Identificar a prevalência de erros que causaram eventos supostamente atribuíveis à vacinação ou imunização.

Método: Revisão sistemática da literatura com metanálise realizada nas bases Medline, Cochrane Library, Cinahl, Web of Science, Lilacs, Scopus; Embase; Open Grey; Google Scholar; e Grey Lit; com estudos que apresentassem prevalência de erros de imunização que causaram eventos ou que disponibilizassem dados que permitissem o cálculo deste indicador.

Resultados: Avaliou-se 11 artigos publicados entre 2010 e 2021, apontando prevalência de 0,044 erros por 10.000 doses administradas (n=762; $IC_{95\%}$: 0,026 – 0,075; $I^2 = 99\%$, $p < 0,01$). A prevalência foi maior em crianças menores de 5 anos (0,334 / 10.000 doses; n=14). Quanto aos eventos, predominou-se: febre, dor local, edema, rubor.

Conclusão: Identificou-se uma prevalência baixa de erros que causaram eventos. Entretanto, os eventos supostamente atribuíveis à vacinação ou imunização podem contribuir para a hesitação vacinal e, consequentemente, impactar nas coberturas vacinais.

Descritores: Imunização. Vacinação. Erros de medicação. Revisão sistemática.

RESUMEN

Objetivo: Identificar la prevalencia de errores que causaron eventos supuestamente atribuibles a la vacunación o inmunización.

Método: Revisión sistemática de la literatura con metaanálisis realizada en las bases de datos Medline, Cochrane Library, Cinahl, Web of Science, Lilacs, Scopus; Embase; Open Grey; Google Scholar; y Grey Lit; con estudios que presentaran la prevalencia de errores de inmunización que causaron eventos o que aportaran datos que permitieran calcular este indicador.

Resultados: Se evaluaron 11 artículos publicados entre 2010 y 2021, indicando una prevalencia de 0,044 errores por cada 10.000 dosis administradas (n=762; $IC_{95\%}$: 0,026 – 0,075; $I^2 = 99\%$, $p < 0,01$). La prevalencia fue mayor en niños menores de 5 años (0,334 / 10.000 dosis; n=14). Los eventos predominantes fueron fiebre, dolor local, edema y enrojecimiento.

Conclusión: Se identificó una baja prevalencia de eventos causantes de errores. Sin embargo, los eventos supuestamente atribuibles a la vacunación o inmunización pueden contribuir a la indecisión sobre la vacunación y, en consecuencia, repercutir en la cobertura vacunal.

Descriptores: Inmunización. Vacunación. Errores de medicación. Revisión sistemática.

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INTRODUCTION

Vaccination can be considered one of the main public health interventions worldwide, contributing to the eradication, reduction of cases and prevention of countless deaths from vaccine-preventable diseases, changing the epidemiological scenario[1,2].

As with the administration of medicines, errors can also occur when vaccinating. One of the factors that contribute to the growth in the number of immunization errors is the considerable increase in immunobiologicals and the complexity of vaccination schedules[3], in addition to inadequate practices in vaccination rooms. Such errors may or may not be accompanied by mild, moderate or even fatal events[4–10], in addition to generating direct and indirect costs for health services[11,12]; reduce the population's confidence in national immunization programs (PNI) and have a direct impact on vaccination coverage and the control and eradication of vaccine-preventable diseases[6,13].

An immunization error is any preventable event in vaccine administration caused by inappropriate use of immunobiologicals and that may be related to inadequate handling, prescriptions and/or administration[14].

Over the years, discussions and studies on immunization errors have been publicized in several countries, as these are the main factors that favor the emergence of events supposedly attributable to vaccination or immunization (ESAVI). Such errors are currently described as serious occurrences and are considered an international problem, directly related to good immunization practices[5–9,13].

The population's low perception of the risk of vaccine-preventable diseases, whether already controlled or with mild symptoms, has led to increased concern about ESAVI. This concern, especially with deaths reported after vaccination, resulted in the discontinuation of vaccination schedules by the population, reducing vaccination coverage worldwide[4]. Furthermore, unlike medicines, vaccines are administered to apparently healthy people, especially children. That said, ESAVI must be monitored to maintain the population's trust in the PNI[15].

Immunization errors can cause severe ESAVI and contribute to vaccine hesitancy. In the current scenario, in which anti-vaccine movements and the dissemination of fake news are growing, other factors that can interfere with the acceptability of vaccines by the population, such as immunization errors, must be prevented.

Providing evidence-based information on the prevalence of immunization errors that caused ESAVI can support the development of organizational strategies, with the aim of ensuring good immunization practices. Furthermore, disseminating this information to healthcare professionals and managers can increase awareness of the importance of safety in vaccination rooms.

In view of the above, the present study aimed to identify the prevalence of errors that caused events supposedly attributable to vaccination or immunization.

METHOD

This is a systematic literature review with meta-analysis developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [16] and registered in the International Prospective Registry of Systematic Reviews (PROSPERO), under identification No CRD42021258335.

The study question was formulated using the PICO strategy: Participants/Population (P): individuals who were vaccinated; Exposure (E): immunization error; Comparison or control (C): not applicable; and Outcome (O): occurrence of ESAVI. Therefore, the following guiding question was created: What is the prevalence of errors that caused events supposedly attributable to vaccination or immunization in vaccinated individuals?

To retrieve potential articles, systematic searches were carried out in seven electronic databases (Medline via Pubmed, Cochrane Library, Cinahl, Web of Science, Lilacs, Scopus and Embase), which covered the available literature from its inception until July 1st 2021 and subsequently updated until October 1, 2022. A specific search strategy was developed for each of the bases, due to their particularities. Boolean operators "OR" and "AND" were used to combine the selected terms, with "OR" being used within intracategories and between variations of terms, and "AND" between categories, combining them with each other. Three categories were considered: Population, Exposure and Outcomes, and no filters were used during the searches. In developing the search keys used, assistance was provided by a librarian with expertise in bibliographic search. In addition to searching the databases, searches were carried out in the gray literature using Open Grey, Google Scholar, Gray Lit and manual search.

The following terms extracted from the Health Sciences Descriptors in Portuguese were used: *Erro, Errado, Imunização, Imunizações, Vacinação, Vacina, Vacinas, Imunizado, Administração de Vacina, Aplicação de Vacina, Efeito Colateral, Reação Adversa, Evento Adverso, Efeito Adverso, Efeitos Adversos, Efeitos Colaterais, Reações Adversas,* and of the Medical Subject Headings in English: Side Effect, Adverse Reaction, Adverse Event, Adverse Effect, Adverse Reactions, Error, Wrong, Immunization, Vaccine, Immunizations, Immunized, Vaccine Administration, Vaccine application and its variations.

Inclusion criteria were primary studies conducted in any healthcare environment that had a prevalence of errors that

caused ESAVI or that provided data that allowed the calculation of this indicator, as well as studies with retrospective analyzes using immunization error reporting systems and/or ESAVI. The occurrence of ESAVI was considered as the main outcome, and the immunization error was considered as the circumstance in which the study participant was exposed.

Intervention studies, systematic reviews, literature reviews, editorials, reviews, experience reports, case studies, summaries published in annals and similar publications, dissertations, theses and monographs were excluded. Intervention or experimental studies were excluded because the systematic review focuses on calculating prevalence, whose primary data came from cross-sectional studies. In this type of observational study, the researcher does not interact with the sample population directly, except through analysis and evaluation obtained through observation[17]. The year of publication, the language of the study or the target audience affected by the immunization error were not defined.

Rayyan[18] software was used in the selection of the studies, at it allows exporting the studies identified in the databases to the software and displaying titles and abstracts, with blinding of researchers. This guarantees reliability in the selection of information, as well as methodological accuracy and precision.

Once the potentially eligible studies were identified, according to pre-established criteria, they were read in full to support the decision on the final sample, using a double blind trial. Studies that raised doubts or disagreements between the two reviewers regarding their eligibility were evaluated by a third reviewer specialized in the subject and subsequently the three reviewers debated their inclusion or exclusion. Likewise, data from the selected studies were independently extracted and entered and analyzed using a Microsoft Excel® spreadsheet. Title, year and country where the study was carried out, period, exposed population, immunization errors that caused ESAVI and number of vaccines administered in the period were extracted. In situations where there was no information available, the study authors were contacted for clarification, and when no response was obtained, the study was excluded. Disagreements between researchers regarding any data collected were resolved by a third reviewer.

To classify the levels of evidence of the studies, recommendations from the literature were used[19], namely: level I: Evidence from a systematic review or meta-analysis of all relevant randomized controlled clinical trials or from clinical guidelines based on systematic reviews of randomized controlled clinical trials; level II: Evidence derived from at least one well-designed randomized controlled clinical trial; level III: Evidence obtained from well-designed clinical trials without randomization; level IV: Evidence from well-designed cohort and case-control studies; level V: Evidence originating from a systematic review of descriptive and qualitative studies; level VI: Evidence derived from a single descriptive or qualitative study; and level VII: Evidence from the opinion of authorities and/or report from expert committees.

Regarding the assessment of risk of bias, all included studies were evaluated using the instrument Appraisal for Cross-Sectional Studies (AXIS)[20]. When selecting this instrument, it was considered that most studies included in the sample had a cross-sectional design. Descriptions of possible sources of bias were mentioned in the study.

To calculate the prevalence of the immunization error that caused ESAVI, the doses administered/dispensed were adjusted to 10,000, in order to allow data comparison. In the calculation, the number of errors that caused the documented ESAVI was used as the numerator, and the number of doses administered/dispensed in the period as the denominator[17]. Prevalence calculations were made separately per article, due to the different profile of data found and also because of their presentation in each article.

Additionally, individual data from the included articles were combined in a random-effects meta-analysis, considering a 95% confidence interval ($CI_{95\%}$). Heterogeneity between estimates generated in individual studies was analyzed using the Q test and the I-square statistic (I^2). Here, I^2 values ≥ 75% were considered indicative of substantial heterogeneity. $P< 0.05$ was considered significant. Analyzes were performed using Comprehensive Meta-Analysis software, version 4.

The types of ESAVI resulting from immunization errors, when detailed in the included articles, were collected, analyzed and classified according to severity (serious and non-serious) and type of manifestation (local and systemic).

RESULTS

The flowchart of the steps taken from the search to the inclusion of articles in this systematic review is shown in Figure 1. A total of 2,071 records were retrieved, through searches in databases, gray literature and manual search, and 634 duplicate studies were removed. Subsequently, the titles and abstracts of 1,437 studies were read, and 42 potentially eligible articles were selected, according to the defined criteria.

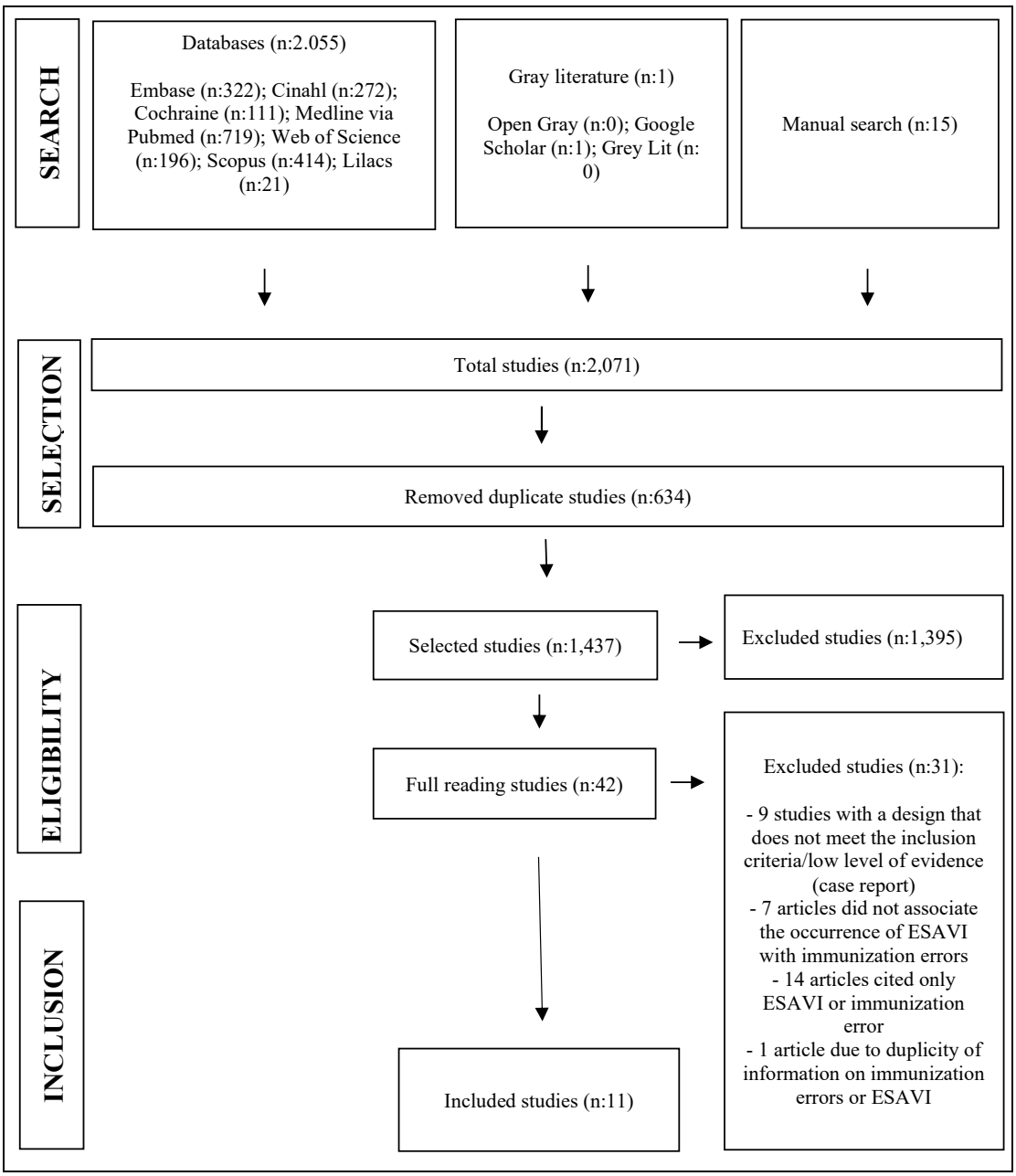
After the full text of the pre-selected studies was read, 11 studies were included in the final sample. Of the 31 excluded studies, nine did not meet the inclusion criteria (type of study), seven did not associate ESAVI with immunization errors and 14 cited only the error or ESAVI. One article was excluded due to duplication of data on immunization errors with ESAVI published by the same author in two articles that evaluated adverse events in pregnant women.

Of the total articles included, six are from Brazil[6–8,10,21,22], four from the United States[12,23–25]; and one from China[26]. The articles analyzed made it possible to point out immunization errors from 2010 onwards. However, the highest concentration of articles occurred in 2020 and 2021[7,10,21,22] (Chart 1).

Four studies were carried out with retrospective analyzes of immunization error reporting systems in Brazil, China and the United States[6,7,22,26]. Three studies from Brazil were carried out to analyze ESAVI[8,10,21]. Three studies were carried out for post-licensing surveillance of vaccines in the United States[23–25]. Finally, one study used the database of a large academic health system through electronic medical records[12] (Chart 1).

In most studies, the sampling population was the general public, which was not separated by age, gender or condition[6,7,22–26]. One study evaluated children under five years of

Figure 1 – Brasil, 2023 PRISMA diagram representing steps conducted in the search and inclusion of articles. Minas Gerais, Brazil, 2023



Source: Elaborated by the authors, 2023.

age[7]; one evaluated a pregnant woman[10], one evaluated children and adolescents between zero and nineteen years old[12] and another study evaluated the elderly population[21]. Four studies included error data on a single vaccine[23–26].

Regarding the type of ESAVI resulting from errors, fever, local pain, edema, flushing were most frequently reported[7,8,12,21,23,25,26]. Among severe ESAVI, the incidence of a hot swollen lump stands out (0.032/10,000 doses applied)[6]; one death after 16 days of administration of a dose of influenza vaccine outside the recommended age[24]; and one study did not specify the ESAVI resulting from errors[22].

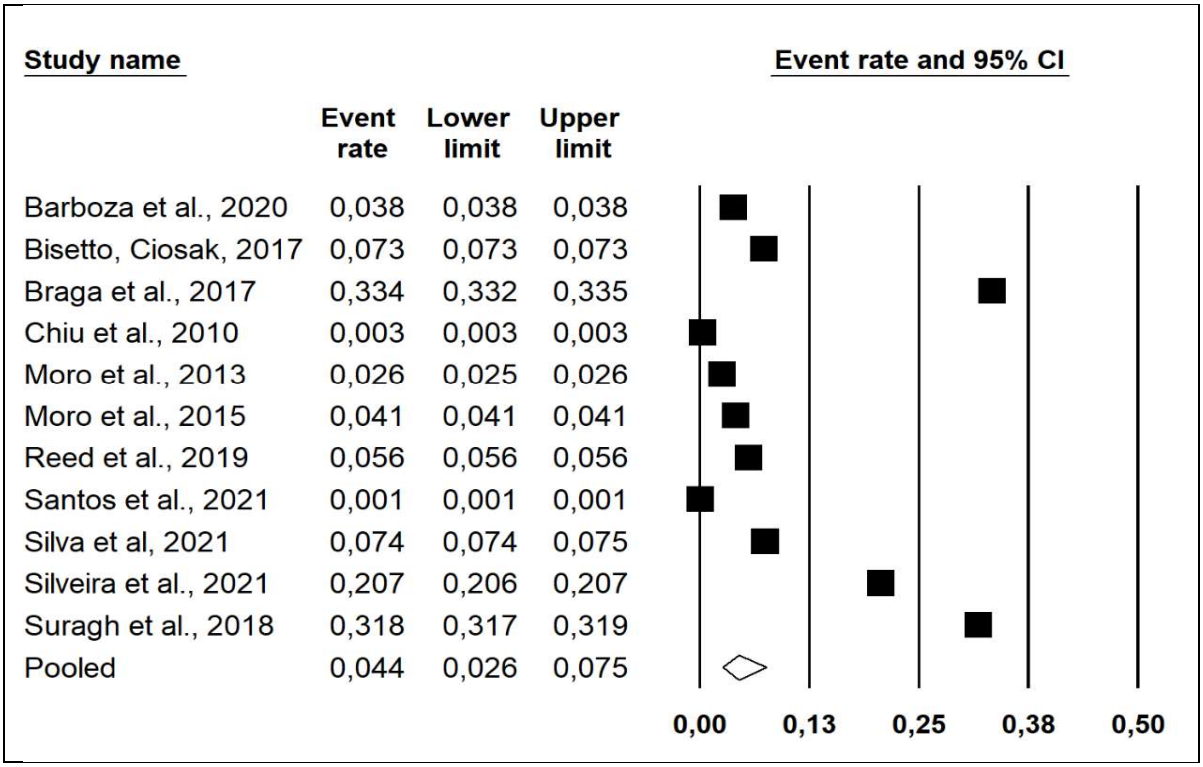
When analyzing vaccine administration errors that generated ESAVI, four studies found that the most common error was related to incorrect dosage[8,12,21,26]; three studies cited doses administered to wrong age groups[12,23,24]; one study cited the wrong interval[7]; two studies cited wrong route[8,12]; and one study did not report the type of error[22].

Table 1 presents for each study included the prevalence of immunization errors that caused ESAVI per 10,000 doses of vaccines administered/dispensed.

As can be seen in figure 2, meta-analysis highlighted the low global prevalence of ESAVI, i.e., 0.044 errors per 10,000 doses administered (n=762; N:139,771,113; CI95%: 0.026 – 0.075; I2 99%, p < 0.01). Taken together, the results presented in Table 1 and Figure 2 show that the highest prevalence was observed in a study carried out with children under the age of five(8); and the lowest in a study carried out with elderly people(21); both in Brazil.

Regarding the assessment of risk of bias or communication practices using the AXIS[20] instrument, of the studies retrieved, five evaluated the collected data that showed a statistically significant association[6,7,10,23,24]. Three studies described the methodology used in a limited way, making it difficult to reproduce it based on the available information[8,25,26]. Five studies did not describe conflicts of interest or financial support[7,21,22,24,25]. Most studies did not mention approval by an ethics committee, which is justified by the fact that they were from a secondary source and there was no need for approval[6,22–26]. Most studies highlighted the limitations encountered during their implementation[6–8,10,12,21–26].

Figure 2 – Meta-analysis of the prevalence of immunization errors with events supposedly attributable to vaccination or immunization. Minas Gerais, Brazil, 2023



Source: Elaborated by the authors, 2023.
Note: Results expressed per 10,000 doses administered; CI: Confidence interval.

Chart 1 – Overview of studies retrieved and included in the final sample (n = 11). Minas Gerais, Brazil, 2023

Authors – Year	Country	Type of study Level of evidence	Objective	Study period	Population studied
Study 1[26] (2010)	China	Epidemiological, descriptive LE*= VI	Determine types of errors and assess critical contributors to the error	11/2009 to 02/2010	General population vaccinated with H1N1
Study 2[24] (2013)	United States	Epidemiological, descriptive LE*=VI	Characterize ESAVI† after administration of the trivalent intradermal inactivated influenza vaccine reported to the United States Adverse Event Reporting System (VAERS‡)	07/2011 to 02/2013	Population vaccinated with Fluzone Intradermal vaccine
Study 3[23] (2015)	United States	Epidemiological, descriptive LE*=VI	Evaluate adverse events following administration of trivalent subunit inactivated influenza vaccine reported to the United States Adverse Event Reporting System (VAERS‡)	07/2013 to 03/2015	General population vaccinated with Flucevax
Study 4[6] (2017)	Brazil	Cross-sectional, descriptive LE*=VI	Analyze the occurrence of ESAVI† resulting from immunization errors, in Paraná, from 2003 to 2013	01/2003 to 12/2013	General population vaccinated in Paraná
Study 5[8] (2017)	Brazil	Cross-sectional, descriptive LE*=VI	Analyze ESAVI† occurring in children under five years of age	07/2012 to 06/2013	Children under five years of age
Study 6[25] (2018)	United States	Epidemiological, descriptive LE*=VI	Review reports submitted to the United States ESAVI Reporting System† (VAERS‡) following bivalent human papillomavirus vaccine from 2009 to 2017 to increase knowledge about its safety	01/2009 to 12/2017	General population vaccinated with bivalent human papillomavirus vaccine
Study 7[12] (2019)	United States	Epidemiological, descriptive LE*=VI	Track and describe the absolute number of vaccine administration errors and corresponding error rates over time and by patient age and vaccine type	01/2016 to 12/2017	Children and teenagers from 0 to 19 years old
Study 8[7] (2020)	Brazil	Cross-sectional descriptive LE*=VI	Analyze immunization errors reported in Goiás between 2014 and 2017	08/2014 to 12/2017	General population vaccinated in Goiás
Study 9[21] (2021)	Brazil	Cross-sectional, descriptive LE*=VI	Analyze the prevalence of ESAVI† in elderly people; raise reported events; identify the vaccines that caused events and verify ESAVI† and the vaccines administered that led to hospitalizations in the State of São Paulo, Brazil, in the years 2015 to 2017	01/2015 to 12/2017	Elderly vaccinated in São Paulo

Chart 1 – Cont.

Authors – Year	Country	Type of study Level of evidence	Objective	Study period	Population studied
Study 10[10] (2021)	Brazil	Epidemiological, descriptive LE*=VI	Analyze the distribution of ESAVI† in pregnant women in the state of Minas Gerais, between 2015 and 2019	01/2015 to 12/2019	Pregnant women vaccinated in Minas Gerais
Study 11[22] (2021)	Brazil	Epidemiological, descriptive LE*=VI	Analyze ESAVI† against SARS-CoV-2 (COVID-19§) in the state of Minas Gerais, Brazil.	01/20/2021 to 03/05/2021	General population

Source: Elaborated by the authors, 2023.
Notes: *LE: Level of evidence; †ESAVI: Events supposedly attributable to vaccination or immunization; ‡VAERS: *Vaccine Adverse Event Reporting System*; §COVID-19: *Corona Vírus Disease*

Table 1 – Prevalence of immunization errors with events supposedly attributable to vaccination or immunization. Minas Gerais, Brazil, 2023

Study – Year	Number of doses administered	Number of immunization errors that caused ESAVI*	Prevalence of immunization errors that caused ESAVI* (per 10,000 doses)
Study 1[26] (2010)	15,000,000	5	0.003
Study 2[24] (2013)	4,700,000	12	0.026
Study 3[23] (2015)	5,600,000	23	0.041
Study 4[6] (2017)	82,527,255	604	0.073
Study 5[8] (2017)	419,689	14	0.334
Study 6[25] (2018)	723,502	23	0.318
Study 7[12] (2019)	1,431,206	8	0.056
Study o 8[7] (2020)	12,362,298	47	0.038
Study 9[21] (2021)	15,196,080	1	0.001
Study 10[10] (2021)	871,070	18	0.207
Study 11[22] (2021)	940,013	7	0.074

Source: Elaborated by the authors, 2023.
Notes: *ESAVI: Events supposedly attributable to vaccination or immunization

DISCUSSION

The findings show that the prevalence of immunization errors that caused ESAVI can be considered low. Although most studies included the general population as participants, the prevalence of these errors associated with ESAVI per 10,000 doses administered ranged from 0.001 in the elderly[21] to 0.334 in children under five years of age[8]. Most of the ESAVI identified were considered mild to moderate. However, one death was reported in an elderly individual who was given a wrong dose of a vaccine, *i.e.* a dose recommended for another age group.

The number of notifications of immunization errors, with and without ESAVI, has been increasing worldwide[6,27,28], directly reflecting the number of studies published in the last five years identified in this review[6–8,10,12,21,22,25]. This increase in the occurrence of errors may be related to several factors, such as the expansion of the vaccination schedule, constant changes and inclusion of new immunobiologicals and, consequently, the complexity of the vaccination schedule[8,11], and the improvement in surveillance of ESAVI[6].

In this review, 27% of the studies retrieved used the Vaccine Adverse Event Reporting System database from the United States[23–25] and 54% used the Post-vaccination Adverse Event Surveillance Information System database from Brazil[6–8,10,21,22].

Both information systems are passive surveillance systems, which may be associated to greater underreporting of cases, due to their no non-mandatory nature [6–7,29] and, consequently, underestimation of the real occurrence of immunization errors. Passive surveillance, despite its low cost and the possibility of maintaining and feeding an information system, has the disadvantage of underreporting ESAVI[6,30].

In most studies, the reported ESAVI immunization errors were considered mild to moderate and caused transient symptoms in vaccinated individuals, and in most cases they did not cause damage or trigger sequelae[5–7,12,21,25,26]. There has been one report of sudden cardiac death after administration of a wrong dose of vaccine (dose not recommended for the patient's age), with no established causal relationship[24].

This generates concern, since even to a lesser extent immunization errors can lead to hospitalization, in addition to dysfunction, sequelae and death[5] and reduce trust and credibility in the health care provided by the PNI[31].

Despite evaluating the general population, the study that used secondary data[6] reported that children under one year of age were the most affected by immunization errors with ESAVI, and that BCG vaccine was responsible for this increase. It is known that children are more likely to develop ESAVI, due to the immaturity of their immune system and the greater number of vaccines administered to this population, considering that the vaccination schedule for this age group is more extensive[12,32,33].

The studies selected and analyzed provided evidence derived from only one methodological design: descriptive cross-sectional[6–8,10,21,22,25,26]. Studies with higher levels of evidence are needed to establish a causal association between outcome and exposure.

The high heterogeneity in the meta-analysis was expected due to the diversity in terms of study population, sample size, type of immunizer, etc., and does not necessarily reflect a weakness of this study. The concentration of studies on immunization errors in Brazil and the United States was considered a limitation. Given that the strength of a review is directly linked to its coverage of studies from different regions of the world, the applicability of the findings of this study is limited.

CONCLUSION

The review identified a low prevalence of immunization errors that caused ESAVI, considering the high number of doses administered. Also, most events identified were considered mild. However, ESAVI, mainly those caused by immunization errors, can contribute to vaccine hesitancy and, consequently, impact vaccination coverage.

This study aims to contribute to assisting health services in adopting appropriate measures to prevent errors, which is essential for safe vaccination; in teaching, based on reflections on patient safety in the vaccination room; and in research pointing out the need for studies on the topic with higher levels of evidence.

REFERENCES

1. Domingues CMAS, Maranhão AGK, Teixeira AM, Fantinato FFS, Domingues RAS. The Brazilian National Immunization Program: 46 years of achievements and challenges. Cad Saúde Pública. 2020;36(Suppl 2):e00222919. doi: https://doi.org/10.1590/0102-311X00222919
2. World Health Organization. 2018 assessment report of the Global Vaccine Action Plan: strategic advisory group of experts on immunization. Geneva: WHO; 2018 [cited 2023 Jun 13]. Available from: https://iris.who.int/bitstream/handle/10665/276967/WHO-IVB-18.11-eng.pdf?sequence=1
3. Condon AJ, Hayney MS. Strategies to minimize vaccine errors. J Am Pharm Assoc. 2016;56(3):339-41. doi: https://doi.org/10.1016/j.japh.2016.03.016

4. Singh AK, Wagner AL, Joshi J, Carlson BF, Aneja S, Boulton ML. Causality assessment of serious and severe adverse events following immunization in India: a 4-year practical experience. Expert Rev Vaccines. 2018;17(6):555-62. doi: https://doi.org/10.1080/14760584.2018.1484285
5. Pacheco FC, Domingues CMAS, Maranhão AGK, Carvalho SMD, Teixeira AMS, Braz RM, et al. Análise do sistema de informação da vigilância de eventos adversos pós-vacinação no Brasil, 2014 a 2016. Rev Panam Salud Publica. 2018;42:e12. doi: https://doi.org/10.26633/RPSP.2018.12
6. Bisetto LHL, Ciosak SI. Analysis of adverse events following immunization caused by immunization errors. Rev Bras Enferm. 2017;70(1):87-95. doi: https://doi.org/10.1590/0034-7167-2016-0034
7. Barboza TC, Guimarães RA, Gimenes FRE, Silva AEBC. Retrospective study of immunization errors reported in an online Information System. Rev Latino Am Enfermagem. 2020;28:e3303. doi: https://doi.org/10.1590/1518-8345.3343.3303
8. Braga PCV, Silva AEBC, Mochizuki LB, Lima JC, Sousa MRG, Bezerra ALQ. Incidence of post-vaccination adverse events in children. J Nurs UFPE on line. 2017;11(Suppl 10):4126-35. doi: https://doi.org/10.5205/1981-8963-v11i10a231174p4126-4135-2017
9. Hoeve CE, van Haren A, Sturkenboom MCJM, Straus SMJM. Spontaneous reports of vaccination errors in the European regulatory database eudravigilance: a descriptive study. Vaccine. 2018;36(52):7956-64. doi: https://doi.org/10.1016/j.vaccine.2018.11.003
10. Silveira IO, Silva TPR, Luvisaro BMO, Silva RB, Gusmão JD, Vimieiro AM, et al. Adverse events following immunization in pregnant women from Minas Gerais. Rev Saude Publica. 2021;55:24. doi: https://doi.org/10.11606/s1518-8787.2021055002592
11. Rodgers L, Shaw L, Strikas R, Hibbs B, Wolicki JE, Cardemil CV, et al. Frequency and cost of vaccinations administered outside minimum and maximum recommended ages-2014 data from 6 sentinel sites of immunization information systems. J Pediatr. 2018;193:164-71. doi: https://doi.org/10.1016/j.jpeds.2017.09.057
12. Reed L, Tarini BA, Andreae MC. Vaccine administration error rates at a large academic medical center and its affiliated clinics – Familiarity matters. Vaccine. 2019;37(36):5390-6. doi: https://doi.org/10.1016/j.vaccine.2019.07.027
13. Hibbs BF, Moro PL, Lewis P, Miller ER, Shimabukuro TT. Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000-2013. Vaccine. 2015;33(28):3171-8. doi: https://doi.org/10.1016/j.vaccine.2015.05.006
14. Ministério da Saúde (BR). Secretaria de Vigilância em Saúde. Departamento de Imunizações e Doenças Transmissíveis. Manual de vigilância epidemiológica de eventos adversos pós-vacinação. Brasília, DF: Ministério da Saúde; 2021 [cited 2023 Jun 13]. Available from: https://docs.bvsalud.org/biblioref/2022/08/1390684/manual_eventos-_adversos_pos_vacinacao_4ed_atualizada.pdf
15. Laryea EB, Frimpong JA, Noora CL, Tengey J, Bandoh D, Sabblah G, et al. Evaluation of the adverse events following immunization surveillance system, Ghana, 2019. PLoS One. 2022;17(3):e0264697. doi: https://doi.org/10.1371/journal.pone.0264697
16. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71. doi: https://doi.org/10.1136/bmj.n71
17. Medronho RA, Bloch KV, Luiz RR, Werneck GL. Epidemiologia. 2. ed. São Paulo: Atheneu; 2009.
18. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev. 2016;5(1):210. doi: https://doi.org/10.1186/s13643-016-0384-4
19. Melnyk BM, Fineout-Overholt E. Evidence-based practice in nursing & healthcare: a guide to best practice. 2. ed. Philadelphia: Lippincott Williams & Wilkins; 2010.
20. Downes MJ, Brennan ML, Williams HC, Dean RS. Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS). BMJ Open. 2016;6(12):e011458. doi: http://doi.org/10.1136/bmjopen-2016-011458
21. Santos LCB, Silva HS, Borja-Oliveira CR, Chubaci RYS, Gutierrez BAO. Eventos adversos pós-vacinação em idosos no Estado de São Paulo, Brasil, de 2015 a 2017. Cad Saude Publica. 2021;37(4):e00084820. doi: https://doi.org/10.1590/0102-311X00084820
22. Silva RB, Silva TPR, Sato APS, Lana FCF, Gusmão JD, Souza JFA, et al. Adverse events following immunization against SARS-CoV-2 (covid-19) in the state of Minas Gerais. Rev Saúde Pública. 2021;55:66. doi: https://doi.org/10.11606/s1518-8787.2021055003734
23. Moro PL, Winiecki S, Lewis P, Shimabukuro TT, Cano M. Surveillance of adverse events after the first trivalent inactivated influenza vaccine produced in mammalian cell culture (Flucelvax®) reported to the Vaccine Adverse Event Reporting System (VAERS), United States, 2013-2015. Vaccine. 2015;33(48):6684-8. doi: https://doi.org/10.1016/j.vaccine.2015.10.084
24. Moro PL, Harrington T, Shimabukuro T, Cano M, Museru OI, Menschik D, et al. Adverse events after Fluzone® Intradermal vaccine reported to the Vaccine Adverse Event Reporting System (VAERS), 2011-2013. Vaccine. 2013;31(43):4984-7. doi: https://doi.org/10.1016/j.vaccine.2013.08.001
25. Suragh TA, Lewis P, Arana J, Mba-Jonas A, Li R, Stewart B, et al. Safety of bivalent human papillomavirus vaccine in the US vaccine adverse event reporting system (VAERS), 2009-2017. Br J Clin Pharmacol. 2018;84(12):2928-32. doi: https://doi.org/10.1111/bcp.13736
26. Chiu P, Huang W, Huang S, Chih Y, Chen C. Program Errors in Taiwan's mass immunizations against pandemic A/H1N1. Taiwan Centers Dis Control. 2010;26(15):268-75.
27. Ferrara P, Masuet-Aumatell C, Ramon-Torrell JM. Acceptance of yellow fever vaccine in the older traveller: a cohort study. Acta Biomed. 2021;92(4):e2021098. doi: https://doi.org/10.23750/abm.v92i4.11619
28. Bonanni P, Zanella B, Santomauro F, Lorini C, Bechini A, Boccalini S. Safety and perception: what are the greatest enemies of HPV vaccination programmes? Vaccine. 2018;36(36):5424-9. doi: https://doi.org/10.1016/j.vaccine.2017.05.071
29. Sebastian J, Gurumurthy P, Ravi MD, Ramesh M. Active surveillance of adverse events following immunization (AEFI): a prospective 3-year vaccine safety study. Ther Adv Vaccines Immunother. 2019;7:2515135519889000. doi: https://doi.org/10.1177/2515135519889000
30. Heininger U, Holm K, Caplanusi I, Bailey SR, CIOMS Working Group on Vaccine Safety. Guide to active vaccine safety surveillance: Report of CIOMS working group on vaccine safety – executive summary. Vaccine. 2017;35(32):3917-21. doi: https://doi.org/10.1016/j.vaccine.2017.06.033
31. Suragh TA, Hibbs B, Marquez P, McNeil MM. Age inappropriate influenza vaccination in infants less than 6 months old, 2010-2018. Vaccine. 2020;38(21):3747-51. doi: https://doi.org/10.1016/j.vaccine.2020.03.039
32. Santos CAPS, Costa RS, Silva JLM, Santos MRF, Gomes BLF. Conhecimento, atitude e prática dos vacinadores sobre vacinação infantil em Teresina-PI, 2015. Epidemiol Serv Saúde. 2017;26(1):133-40. doi: https://doi.org/10.5123/S1679-49742017000100014
33. Batista ECC, Ferreira AP, Oliveira VC, Amaral GG, Jesus RF, Quintino ND, et al. Active surveillance of adverse events following immunization in primary health care. Acta Paul Enferm. 2021;34:eAPE002335. doi: https://doi.org/10.37689/acta-ape/2021AO002335

Acknowledgments:
The present study was carried out with the support of the Coordination for the Improvement of Higher Education Personnel (Code 001) and the National Council for Scientific and Technological Development (Protocol no 420760/2018-0). The authors would like to thank Prof. Vinícius Silva Belo (Universidade Federal de São João del-Rei) for conducting the meta-analysis, and librarian Gesner Francisco Xavier Junior (Faculdade de Medicina of Universidade Federal de Minas Gerais) for structuring the research protocol.

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The authors declare that there is no conflict of interest.

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ERRATUM:
This article has an erratum:
https://doi.org/10.1590/1983-1447.2024.20230097er.en

Received: 06.16.2023
Approved: 09.25.2023
Corrected: 05.13.2024

Associate editor:
Carlise Rigon Dalla Nora

Editor-in-chief:
João Lucas Campos de Oliveira