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ORIGINAL ARTICLE

EudraVigilance insights: Suspected adverse drug reactions in infants through breastfeeding

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Aims: We aimed to describe suspected adverse drug reactions (ADRs) in infants resulting from medications transmitted through mothers' milk, as reported to the European ADR database, EudraVigilance. The research sought to understand the frequency, seriousness and nature of these ADRs to assess potential risks associated with maternal medication use during breastfeeding.

Methods: Data from EudraVigilance were analysed. The study included all reported ADRs suspected to be related to medications transmitted through mothers' milk from 1 January 2013 to 1 July 2023. The data were categorized by reporting time, infant age and sex, seriousness and type of ADR, and the medications involved.

Results: A total of 922 suspected ADRs were reported in breastfed infants. Serious ADRs accounted for 133 cases (14%), with 15 reported fatalities, primarily associated with methadone ($n = 11$) and diamorphine ($n = 3$). COVID-19 vaccines were linked to half of the suspected ADR reports ($n = 479$, 52%), while serious ADRs were mainly associated with nervous system drugs ($n = 73$, 43%), particularly anticonvulsants and opioids. Most cases ($n = 511$, 55%) occurred in infants aged between 1 month and 1 year.

Conclusions: The reporting of 922 ADRs in breastfed infants over a decade, compared to the estimated millions of infants exposed to medications via mothers' milk annually in Europe, suggests a very low reporting rate of suspected ADRs. This finding emphasizes the significant challenges in postmarketing surveillance and suggests that underreporting remains a critical concern in pharmacovigilance.

KEYWORDS
breastfeeding, infant exposure, opioids, postmarketing safety surveillance, side effects

1 | INTRODUCTION

Breastfeeding is considered the best source of nutrition for infants, benefiting both them and their mothers.[1] Studies show that over half of breastfeeding women in Europe use medications,[2–4] many of which can pass into mothers' milk, exposing infants.[5,6] While most medications are believed to be safe, there are documented cases of infant toxicity.[5–7]

Despite the importance of understanding medication safety during breastfeeding, clinical trials in pharmacology frequently exclude

breastfeeding women and their infants due to practical and safety concerns.[8,9] This leaves gaps in knowledge about medication safety.[8,9]

Spontaneous reporting of suspected adverse drug reactions (ADRs) is a fundamental component of postmarketing safety surveillance for medicinal products.[10] Spontaneous ADR reporting includes reports submitted by healthcare professionals or patients on their own initiative regarding adverse drug reactions, without being directly requested by health authorities or manufacturers.[11] Limited studies have previously been conducted on spontaneously reported adverse reactions in infants suspected to stem from medication in breast milk.[12,13] The European pharmacovigilance database, EudraVigilance, managed by the European Medicines Agency, is employed for managing individual ADR reports.[11] This system includes suspected ADRs related to medicines or vaccines authorized within the European Economic Area, containing all reports from healthcare and nonhealthcare professionals to national competent authorities in the European Union or to marketing authorization holders.[14] This makes EudraVigilance 1 of the largest spontaneous reporting systems worldwide.[11]

Across Europe, many mothers breastfeed for several months,[15] potentially exposing their infants to medication through milk, but the potential ADRs in the infants are not clarified. This study aimed to systematically describe the suspected ADRs in infants potentially resulting from medications transmitted through mothers' milk. It used 10 years of spontaneous report data from the EudraVigilance system, which primarily covers the European Union and European Economic Area countries. During the observation period, the European Union and European Economic Area countries had a population of about 500 million, with approximately 4 million births per year and thus millions of breastfed infants.[16]

What is already known about this subject

- Recognized gaps in data on medication safety through breast milk due to research exclusions.
- Known instances of infant toxicity from medications like codeine in breastfed infants.
- EudraVigilance provides a critical, extensive dataset for adverse drug reaction reporting.

What this study adds

- Documents a low reporting rate of suspected adverse drug reactions from medications in breast milk over 10 years.
- Identifies medications most linked to adverse reactions, highlighting underreporting issues.
- Calls for better reporting systems and research to ensure medication safety during breastfeeding.

2 | METHODS

2.1 | Study design

This observational study investigated suspected ADRs in infants potentially induced by medications transmitted through mothers' milk. It used spontaneous report data submitted to EudraVigilance. The study covered a period from 1 January 2013 to 1 July 2023.

2.2 | Outcome

The outcome included the types, seriousness and frequencies of suspected ADRs, as well as the specific medications involved.

2.3 | Data collection and categorization

Data on ADRs were extracted from EudraVigilance, which gathers reports from healthcare professionals and consumers across the European Economic Area.[11] The study included reports of suspected ADRs in infants, which were potentially related to medications consumed by breastfeeding mothers defined by the Standardized Medical Dictionary for Regulatory Activities (MedDRA) Query: Neonatal Exposures via Breast Milk.[17]

ADRs were systematically categorized by type, seriousness, patient age and sex. Reactions were classified as serious if they resulted in death, were life-threatening, necessitated hospitalization or an extended hospital stay, or led to persistent or significant disability.[18] Reactions not meeting these criteria were categorized as nonserious.[18] The reactions were classified using the MedDRA at the Preferred Term level.[17]

2.4 | Statistical analysis

Descriptive statistics were used to analyse the frequency and distribution of ADRs. The data were grouped by patient age and sex, type of medication and the nature of the ADRs. Fatal cases received separate, detailed analysis.

2.5 | Ethical considerations

Access to the EudraVigilance database was obtained from the European Medicines Agency, ensuring ethical compliance in healthcare data research. The European Medicines Agency permits researchers, healthcare professionals and the public to examine and analyse ADR reports, promoting transparency and enhancing drug safety surveillance.[19] Detailed case descriptions and narratives were not available.

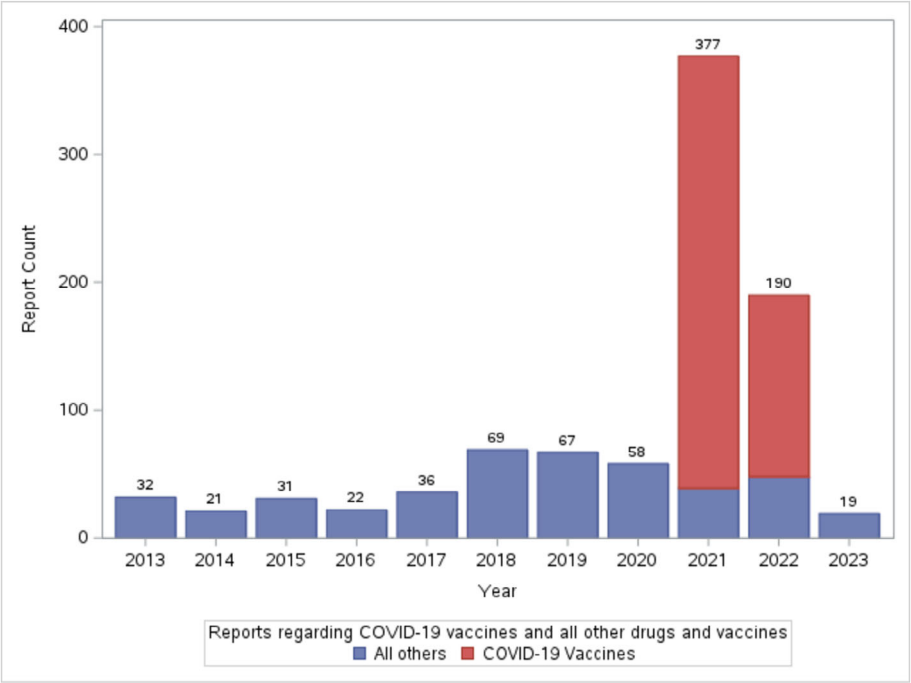

FIGURE 1 Annual suspected adverse drug reaction (ADR) reports. Annual count of reported ADRs in breastfed infants from 1 January 2013 to 1 July 2023, caused by medications transferred to the infant through mothers' milk. Note that the data for 2023 only cover the first half of the year, up to 1 July.

TABLE 1 Age distribution and seriousness of adverse drug reactions (ADRs) in infants.

Infant age group	Total ADRs, *n*	Serious ADRs, *n* (%)	Fatal ADRs, *n* (%)
Not known	105	23 (22%)	0 (0.0%)
<1 month	157	47 (30%)	7 (4%)
1 month - 1 year	511	53 (10%)	8 (2%)
>1 year	149	10 (7%)	0 (0%)
Total	**922**	**133 (14%)**	**15 (2%)**

Note: This table shows the distribution of suspected ADRs in breastfed infants by age group, providing the total number of ADRs along with a breakdown of serious cases (including fatal) and fatal cases. Percentages are calculated based on the total number of ADRs within each age group.

3 | RESULTS

In total, 922 ADRs in breastfed infants were reported to EudraVigilance between 1 January 2013 and 1 July 2023. Among the ADR reports, 355 (39%) were reported in boys, 323 (35%) in girls and 244 (26%) did not have the sex specified. The number of ADR reports varied significantly over the years, with a notable surge in 2021 and 2022. This increase was primarily driven by reports related to COVID-19 vaccinations, which were introduced to the market in 2020 but accounted for 52% (479 out of 922) of the total reports over the 10-year period (Figure 1).

Fifteen cases (2%) were fatal. Of these, 11 cases were after maternal exposure to methadone and 3 were after maternal exposure to diamorphine. For 10 of the fatal cases, there were reports of maternal exposure to a single medication transmitted to infants through breast milk (range: 1 to 4 medications).

Reports on the seriousness showed that 469 (51%) reports were categorized as nonserious and 133 (14%) were serious, while 320 (35%) reports lacked categorization. Data on seriousness and fatality of ADRs in relation to infant age are detailed in Table 1.

TABLE 2 Top 10 medications associated with adverse drug reactions (ADRs) overall.

Medication	Total ADR reports, *n*
COVID-19 mRNA vaccine	384
COVID-19 viral vector nonreplicating vaccine	95
Desogestrel	20
Levetiracetam	18
Lamotrigine	17
Paracetamol	15
Methadone	11
Valproic acid	11
Amoxicillin and β-lactamase inhibitor	10
Sertraline	9

ADRs predominantly affected infants aged 1 month to 1 year, accounting for 511 (55%) of the reports. The youngest infants, under 1 month, were involved in 157 reports (17%), while those older than 1 year featured in 149 reports (16%). Among the serious ADRs, infants younger than 1 month experienced a higher proportion of

TABLE 3 Top 10 medications associated with serious adverse drug reactions (ADRs).

Medication	Serious ADR reports, *n*
COVID-19 mRNA vaccine	21
Levetiracetam	9
Lamotrigine	6
Methadone	11
Valproic acid	7
Ocrelizumab	6
Topiramate	4
Codeine	3
Diamorphine	3
Insulin glargine	3

serious outcomes, including 47 cases (30% of age group), with 7 being fatal. In comparison, infants aged 1 month to 1 year had 53 serious ADRs (10% of age group), with 8 fatalities.

The distribution of the ADRs by medication type is summarized in Table S1. The majority of ADRs in breastfed infants were associated with anti-infectives for systemic use including vaccines ($n = 566$, 55%), followed by nervous system medications ($n = 172$, 17%), while serious ADRs were predominantly linked to nervous system drugs ($n = 73$, 43%). Among nervous system medications, anticonvulsants such as levetiracetam, lamotrigine, valproic acid and topiramate, along with opioids including methadone and diamorphine, were notably linked to ADRs in breastfed infants.

The 10 most frequently reported medications are listed in Table 2, including COVID-19 mRNA vaccines ($n = 384$), COVID-19 viral vector nonreplicating vaccines ($n = 95$) and the hormonal contraceptive desogestrel ($n = 20$). The 10 most frequent medications linked to serious ADRs are listed in Table 3.

The 25 most common specific reactions reported are summarized in Table S2, with pyrexia being the most frequently reported ADR, accounting for 152 cases. Other common reactions reported included vomiting and diarrhoea. Among the serious ADRs, pyrexia, vomiting and diarrhoea were most frequent. For a comprehensive list of serious reactions, please refer to Table S3.

4 | DISCUSSION

This large, multinational European study uses the best available central registry data to examine suspected ADRs in infants linked to maternal medication transmitted through breast milk. Despite the annual birth rate of around 4 million children in Europe,[16] there were only 922 reported ADRs from medications transmitted through breast milk over a period of 10 years. We estimated that at least 20 million breastfed infants might have been exposed to medications during the study period,[2–4] yielding an ADR reporting rate of about 4.61 per 100 000 exposed infants. This low rate could suggest that such reactions are either exceedingly rare or significantly underreported, which could distort our understanding of the safety profiles of medications used during breastfeeding. A cohort study has shown that ADRs in breastfeeding children are quite common, occurring in approximately 10% of cases after maternal medication intake.[7]

The spontaneous ADR reporting system has many well-documented limitations, and the data it generates should be interpreted with caution.[20,21] However, breastfeeding mothers are not typically included in Phase III trials, which means that the safety of medications for breastfed infants is not well-established by the time these medications enter the market, making spontaneous ADR reporting 1 of the few available options for gathering information on ADRs.

The study acknowledges the inherent limitations of passive surveillance systems, including underreporting and the absence of a verified causal relationship between the medication exposure and the ADR.[10] Furthermore, reports for certain medication groups may be distorted due to various factors, including heightened public vigilance toward specific medications like vaccines.[22] Therefore, the findings should be interpreted within the context of these limitations.

An example where media attention has probably led to numerous reports is the many reports concerning COVID-19 vaccination (Figure 1). While small amounts of mRNA may be briefly detectable in breast milk, there is no evidence to suggest they survive passage through the infant's gastrointestinal tract or harm breastfeeding infants.[23,24] In contrast, breast milk from vaccinated individuals contains SARS-CoV-2-specific antibodies and T cells, which benefit the infant's developing immune system.[25,26] Overall, the evidence suggests that there is no risk to infants from breastfeeding by mothers who have received the COVID-19 vaccine and, indeed, there may be some potential benefits.[23,27]

However, there are reports in the study that warrant further exploration. For example, fatal cases were primarily attributed to methadone, and deaths among infants linked to this medication have been reported previously.[28] A particular challenge in investigating ADRs in infants who receive medication through breast milk is that these infants may also have been exposed in utero. Generally, the cord: maternal plasma ratio exceeds the milk: maternal plasma ratio, indicating greater prenatal exposure.[6,29,30] Like other opioids, methadone passes into breast milk, and the relative infant dose has been reported to range between 1 and 6%.[31] A Canadian study involving 85 675 new mothers and their infants demonstrated that infants born to mothers who were prescribed opioids postdelivery did not face a higher risk of adverse outcomes compared to those born to mothers who were not prescribed opioids.[32] However, this study did not include mothers who were using methadone or diamorphine.[32] Methadone and diamorphine are medications that are often used regularly, leading to higher exposure of the infant compared to single doses of opioids. Moreover, misuse of methadone and diamorphine is often associated with lifestyle factors linked to adverse infant outcomes. It is also important to note that the exact doses received by the women are not known, and doses could potentially be supratherapeutic. Due to dataset limitations, distinguishing between prescribed and nonprescribed drug use is challenging, and the lack of detailed case narratives complicates further analysis.

Many of the ADRs identified in our data are linked to anticonvulsants. It is well-known that these substances are generally transferred to breast milk to a large extent, thereby posing a risk of ADRs in breastfed infants.[33] Although robust evidence is not available, it is often recommended that mothers with epilepsy continue breastfeeding while being treated with anticonvulsants.[34,35] The few ADRs in this dataset do not alter this status.

Our findings emphasize the need for a balanced approach to evaluating medication safety in breastfeeding mothers, highlighting the challenges in postmarketing surveillance and the likely underreporting of ADRs, a longstanding concern in pharmacovigilance.[36] Medication safety concerns can affect a mother's decision to start or continue breastfeeding, with many ceasing earlier than desired due to medication-related worries.[37,38] This underscores the need for enhanced support and clearer communication to assist mothers in making informed decisions about medication during breastfeeding. It is important to weigh the substantial benefits of breastfeeding against the potential risks of drug exposure. This necessitates not only better reporting systems but also increased awareness among healthcare providers and parents regarding the importance of reporting suspected ADRs. Furthermore, these results point to the need for additional pharmacokinetic, clinical and epidemiological studies, given the limited data available from spontaneous reports.

Future research should aim to enhance the quality and completeness of data to better understand the causal relationships and clinical outcomes of drug exposure during breastfeeding. Prioritization should be given to drugs that are essential for breastfeeding mothers, such as anticonvulsants. The field is well-acquainted with the methodologies necessary to ensure drug safety. The challenge lies in applying these effectively to the specific patient group of mother–infant pairs. This would help in refining guidelines and recommendations for medication use in breastfeeding women, ensuring both maternal and infant health.

AUTHOR CONTRIBUTIONS

All authors contributed to the study conception and design. D.R.G., H.H., J.T.A., C.G., U.L.T. and R.H.O. performed data collection and analysis. I.H. wrote the first draft of the manuscript, and all authors reviewed and commented on subsequent versions. All authors read and approved the final manuscript.

CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to disclose.

DATA AVAILABILITY STATEMENT

Access to data from EudraVigilance can be obtained by applying to the European Medicines Agency.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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