

Review Article

Medication Safety in Breastfeeding Mothers. The Current Situation in the Greek National Healthcare System

Tigka Maria^{1, 2*} , Nanou Christina¹, Lykeridou Aikaterini¹, Metallinou Dimitra¹

¹Department of Midwifery, School of Health and Care Sciences, University of West Attica, 28 Ag. Spyridonos Str., GR-12243, Athens, Greece

²Department of Obstetric Emergency, General and Maternity Hospital "Helena Venizelou", 2 Elenas Venizelou Str., GR-11521, Athens, Greece

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Abstract: Mothers during lactation may encounter barriers including the need of medication intake due to a chronic or acute illness, which may affect mainly the duration of breastfeeding. In these cases, the issue of medication safety during lactation arises and maternal decisions usually depend on professional counseling. Providing scientifically valid information on the benefits of breastfeeding and the risk of exposure of the newborn/infant to medicines through breast milk is a responsibility of healthcare professionals. Reliable sources on the compatibility of medicines with breastfeeding vary and the information among them is conflicting or even insufficient, creating as a consequence difficulty for healthcare professionals to provide counseling. Given the fact that breastfeeding mothers are excluded from clinical trials as they are considered a vulnerable population, the scientific community has turned to alternative methods based on pharmacokinetic population modeling for medication safety during lactation. In addition, through pharmacovigilance science, databases related to drug compatibility with breastfeeding can be enriched with new data. Undoubtedly, the contribution of midwives and other healthcare professionals involved in breastfeeding plays a key role in the pharmacovigilance process through the observation and reporting of side effects. In the Greek national healthcare system, telephone helplines have been established to provide information on medication safety during lactation. Finally, information is provided on the guiding principles for midwives and other healthcare professionals regarding medication safety in breastfeeding mothers. The ultimate goal is to support and prolong breastfeeding with evidence-based knowledge.

Keywords: Medication, Safety, Breastfeeding, Greek healthcare system.

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INTRODUCTION

Breastfeeding is regarded as the key element of a child's health, as it offers a number of nutritional ingredients and bioactive compounds for the development and strengthening of the immune system. The advantages of breastfeeding for the mother-child dyad in the short and long-term have been demonstrated through a number of scientific studies (McAdams, 2021; Mosca & Gianni, 2017). Therefore, exclusive breastfeeding (EBF) is considered the "gold standard" for infant nutrition for the first 6 months of life by international organizations, including the American Academy of Pediatrics (AAP), the World Health Organization (WHO) and the Association of Women's

Health, Obstetric and Neonatal Nurses (AWHONN) (Spatz, 2012).

Our era is characterized by a "shift to breastfeeding", which probably derives from the growing awareness of the benefits of breastfeeding and the trend away from formula feeding, due to increased emphasis on breastfeeding promotion and encouragement. However, mothers in their efforts to maintain breastfeeding may face barriers that impact on the initial goals they had set regarding its duration. Such situations may include maternal conditions requiring medication, such as chronic or acute illnesses and medical emergencies demanding diagnostic imaging or even

*Corresponding Author: Maria Tigka

Department of Midwifery, School of Health and Care Sciences, University of West Attica, 28 Ag. Spyridonos Str., GR-12243, Athens, Greece

surgery. In these cases, the issue of the compatibility of administered medications with breastfeeding arises, and the mother's decision often depends on the evidence-based counseling provided by a qualified healthcare professional, i.e., a midwife or a pediatrician (Shamir, 2016; Tigka *et al.*, 2022a). This is a critical concern as mothers are expected to make informed decisions about whether to continue breastfeeding while on medication or not. Hence, healthcare professionals should aim to provide scientifically valid information on the advantages of breastfeeding and the potential risk of exposure of the newborn/infant to medicines through breast milk, based on current research and updated guidelines.

Compatibility of medications with breastfeeding

Most medications have not been linked to side effects on lactating women or/and the nursing child. This important information can be used to reassure breastfeeding mothers that many medicines can be used safely during lactation. Even a short-term interruption of breastfeeding can cause difficulties in the mother-child dyad, which underlines the importance of finding safe solutions that allow breastfeeding to continue whenever possible, especially when the mother is in need of medication intake. Lactating women should be informed about reliable sources of information regarding medication intake during lactation and, finally, encouraged to “shared – decision making” (Al-Sawalha *et al.*, 2016; Tigka *et al.*, 2022a). Contemporary sources that mothers and healthcare professionals can consult regarding medication compatibility during lactation are presented in Table 1.

Table 1: Reliable sources with information regarding medications' compatibility with breastfeeding

Source of information	Comments
Hale's Medication and Mother's Milk: A manual of lactational pharmacology by Thomas Hale.	This manual is the work of a globally renowned specialist in perinatal pharmacology, Dr Thomas Hale, containing evidence-based and up-to-date information on the excretion of drugs in human breast milk. The manual includes Hale's classification of medications according to their compatibility with breastfeeding (L1: compatible, L2 & L3: possibly compatible, L4: possibly hazardous, L5: hazardous). Dr. Thomas Hale directs the Infant Risk Center (https://www.infantrisk.com/about-infantrisk-center) which is a global call center for parents and healthcare professionals. It provides information on the risks for the newborn/infant deriving from maternal medication use, with the ultimate goal of breastfeeding support and prolonged continuation of breastfeeding.
https://www.ncbi.nlm.nih.gov/books/NBK501922/ Drugs and Lactation Database – Lactmed.	The LactMed database includes information on medicines and chemical substances that lactating women are likely to be exposed to. It also provides data about the levels of these substances found in breast milk and newborn/infant's circulation, as well as possible adverse reactions in the nursing newborn/infant. In addition, it provides suggested therapeutic alternatives to these medicines, where indicated. The data are all extracted from peer reviewed literature. An expert panel reviews the data on a frequent basis to ensure that they are scientifically valid and updated.
https://doi.org/10.1542/peds.2013-1985 American Academy of Pediatrics (AAP). The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update on Selected Topics.	This is an article from the American Academy of Pediatrics (Sachs <i>et al.</i> , 2013). This report addresses the use of psychotropic medicines, medicines for the treatment of substance abuse, drugs, galactagogues, herbal products and immunization agents in breastfeeding women.
https://www.breastfeedingnetwork.org.uk/drugs-factsheets/ The Breastfeeding Network	This is a Scottish-based information center for mothers and healthcare professionals on breastfeeding-related medicines and diseases. It provides a telephone helpline.
https://apps.who.int/iris/handle/10665/62435 Breastfeeding and Maternal Medication. Recommendations for Drugs in the Eleventh WHO Model List of Essential Drugs.	This report, under the auspices of the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF), outlines a list of medicines and categorizes them according to their compatibility with breastfeeding (1. Compatible with breastfeeding, 2. Compatible with breastfeeding. Monitor infant for side effects, 3. Avoid if possible. Monitor infant for side effects, 4. Avoid if possible. May inhibit lactation, 5. Avoid).
https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/breastfeeding-and-lifestyle/medicines/ National Health Service (England)	This is the website of the National Health Service of England. It provides reliable information.
https://www.drugs.com/drug-safety-breastfeeding.html	This site delivers unbiased data aligned for the healthcare professional community, derived exclusively from reliable and

Source of information	Comments
Drugs.com	independent sources such as the American Society of Health-System Pharmacists (ASHP), the U.S. Food and Drug Administration (FDA), Truven Health Analytics, Harvard Health and Cerner Multum.
https://e-lactancia.org e-lactancia	Index of breastfeeding-related medicines from a hospital in Spain. E-lactancia is a project of APILAM (Association for the promotion and scientific research on breastfeeding).

Barriers for breastfeeding mothers and healthcare professionals

The complexity in decision-making for breastfeeding mothers regarding medication use during lactation and the challenges in providing evidence-based counseling by healthcare professionals are other aspects reported in this section. Research reports in the literature have shown that in several cases mothers have been erroneously led to weaning or have avoided taking necessary medications alongside breastfeeding due to fears of potential adverse events on their newborns/infants or due to incorrect counseling by healthcare professionals (Odom *et al.*, 2013; Saha *et al.*, 2015). This fact highlights the need for accurate and evidence-based information. In many cases, information on the use of medicines during lactation may be inadequate or even conflicting, making it challenging for healthcare professionals to perform counseling (McClatchey *et al.*, 2018). In order to weigh up the potential risks and benefits of breastfeeding, healthcare professionals should take multiple factors into account. Among these factors are the mother's necessity for the medicine, the possible impact of the medicine on milk production, the extent to which the medicine is excreted in the breast milk, the degree of absorption by the nursing newborn/infant, and possible adverse effects on the latter (Sachs *et al.*, 2013). Infant age may also be a significant determinant in the decision-making process, as adverse reactions attributed to exposure to medicines through breastfeeding occur most frequently in infants less than two months of age and rarely in infants older than six months (Anderson *et al.*, 2016).

Data enrichment on medication use during lactation

In order to facilitate the safety of medication intake during lactation, and given the fact that breastfeeding mothers are excluded from clinical studies due to being considered a vulnerable population (Verstegen & Ito, 2019), alternative methods based on population pharmacokinetic modeling have been developed. These methods provide simulation-based assessments of the infant's drug exposure through breast milk (Wald *et al.*, 2022; Weisskopf *et al.*, 2020). An adverse reaction in a breastfeeding infant attributed to maternal medication use may be the result of an interaction of factors between the mother and the infant, a complex scenario that can be well investigated using physiologically-based pharmacokinetic modeling (PBPK). PBPK modeling, considering complex factors such as genetics, time-varying physiology or co-administered drugs, is a useful tool for the prediction of infant drug exposure. This approach may be used to aid

benefit-risk decisions regarding both the lactating mother and the infant even during early drug development (Pan & Rowland, 2022).

There is a continuous attempt to update information on medicines used during lactation, as evidenced by the fact that the fraction of medicines for which no data is available decreases over time. Very recently, Fomina *et al.*, (2023) assessed the extent to which evidence-based information is provided to breastfeeding women regarding the most common medications taken during lactation. According to the Lactmed database, only 10% of the drugs had no data available from research studies (Fomina *et al.*, 2023), compared to older studies that used different databases and reported a rate of 35.8-37.2% of medicines with no available data (Chaves *et al.*, 2007; Olesen *et al.*, 1999). Additionally, there are continuing attempts around the world to gather more information on the safety of medications during lactation. In 2014, the Food and Drug Administration (FDA) issued the Pregnancy and Lactation Labeling Rule (PLLR) which compels pharmaceutical companies to disclose thorough information about drug compatibility with pregnancy and lactation (Byrne *et al.*, 2020).

Furthermore, through the science of pharmacovigilance, databases related to the compatibility of medicines with breastfeeding can be enriched with new data. The World Health Organization defines pharmacovigilance as the science and process that aims to identify, evaluate, understand and prevent adverse reactions or other problems associated with the use of pharmaceutical products (WHO, 2022). Because the number of patients participating in clinical trials before a medicine is approved is limited, rare and more serious adverse reactions do not usually occur in this phase. After the marketing authorization of a medicinal product, the reporting of suspected adverse reactions is initiated by the healthcare professionals who observe them and additional information is subsequently collected. Post-approval pharmacovigilance of a drug uses tools and research methods to identify unknown adverse effects (Ntaountakis & Apostolakis, 2010).

The European Union has set up its own pharmacovigilance system, the European Medicine Agency (EMA). The EMA requires marketing authorization holders of medicinal products to submit all reports they receive through an electronic process. For medicinal products for human use, EC Regulation No 726/2004 and EU Directive 2001/83/EC apply. The

system maintained by the EMA includes data on all suspected adverse reactions recorded by EU Member States and is called Eudravigilance (EMA, 2019). Greece has the national pharmacovigilance committee of the EOF to which, according to the current regulation, pharmaceutical companies and hospitals are required to report adverse reactions which they are made aware of by any means. The Yellow Card, which exists in all countries of the European Union, is the tool for spontaneous reporting and notification of adverse reactions to the National Medicines Agency (EOF). Its completion is simple and short, and the information contained in it is confidential and handled with particular sensitivity by the EOF (EOF, 2022; Ntaountakis & Apostolakis, 2010).

Healthcare professionals and pharmacovigilance

The role of healthcare professionals is of paramount importance in reporting adverse reactions to medicines. In the case of breastfeeding mothers, it is usually a midwife, pediatrician, obstetrician or/and a pharmacist who are called upon to identify whether an adverse event is causally related to the medication the breastfeeding mother is taking or is a symptom of the disease for which she is receiving the medication. There is a growing interest in pharmacovigilance in the perinatal period by midwives and other healthcare professionals (Alan *et al.*, 2013; Barlow-Mosha *et al.*, 2022; Nosedá *et al.*, 2021). In the study by Barlow-Mosca *et al.*, (2022), trained midwives collected data from African mothers and estimated the prevalence of spinal cord lesions in women receiving antiretroviral treatment during pregnancy. Nosedá *et al.* (2021) investigated the adverse effects of the human monoclonal antibodies erenumab, galcanezumab and fremanezumab used to treat migraines in pregnant and breastfeeding women, based on data from VigiBase, a global database of the WHO. No cases of toxicity in mothers, serious birth defects in fetuses or increased miscarriage rates in pregnant women were reported. After a thorough literature review, only the study by Sussan *et al.*, (2014) focused on pharmacovigilance during breastfeeding, which described spontaneous reports of adverse drug reactions transmitted through breast milk, data based on the French pharmacovigilance database. Adverse reactions were reported by healthcare professionals in 88.7% of cases and the rest by the mothers themselves. The most common adverse effects were associated with the nervous system and the gastrointestinal tract. The suspected drugs included antiepileptics, opioid analgesics and benzodiazepines. Finally, a survey of particular interest was conducted in Turkey in 2010 on midwives' and nurses' knowledge of the definition of pharmacovigilance and their experience in reporting adverse drug reactions. The results showed that only 23.3% of the sample identified the definition of pharmacovigilance accurately, while only 1.2% was aware of the adverse event reporting center nominally (Alan *et al.*, 2013).

In the Greek setting, to our knowledge, no studies have been conducted on pharmacovigilance by midwives during the perinatal period. Nevertheless, midwives can contribute actively to detecting, assessing, understanding and preventing adverse reactions caused by medication intake during the perinatal period. The augmented and sufficient collection of data and their early assessment would enable mothers and midwives to obtain the information required in order to support the shared decision-making process on medication use during lactation and provide the scientific and regulatory authorities with new data (Tigka *et al.*, 2022b). Therefore, further research in this field is required. Moreover, few Greek studies have been conducted until now, mainly focused on the detection and reporting of adverse drug reactions regarding administration of antibiotics in pediatric patients and the general population by physicians and nurses. Rates of reporting adverse drug reactions by the aforementioned healthcare providers are low either due to underestimation of the severity of the reactions, or because of lack of recognition of their obligation to follow the procedure and work overload (Geitona *et al.*, 2022). Although the incidence of adverse drug reactions was higher among nurses than physicians (44.8 vs 23.7%), the former reported a higher rate (63 vs 32.7%) of never having reported to the authorities (Toska *et al.*, 2014). The low reporting rates continue to be a major concern; thus ongoing educational programs on pharmacovigilance are required among health sciences. In the Greek context, although there are postgraduate programs in pharmacoepidemiology and pharmacovigilance, the majority are oriented towards doctors, pharmacists, nurses, chemists, biologists, biochemists, with midwives seeming to be excluded from the application procedures for attendance.

Greek policies for providing information on medication intake during lactation

Breastfeeding promotion is dependent on the execution of national policies and recommendations at all levels of the health and social system to establish breastfeeding as the standard for child nutrition (EU Project, 2004). In the context of supporting breastfeeding, most European countries offer centralized telephone-based specialized medical information on potential drug toxicity, where healthcare professionals and mothers can obtain information 24 hours a day. In Greece, there is a national program called "Alkyone" that is run by the Directorate of Social and Developmental Pediatrics of the Institute of Child Health, which aims to raise public awareness, support lactating women and provide information to healthcare professionals. "Alkyone" operates a nationwide telephone helpline which was launched around the end of 2013, offering mothers the opportunity to resolve questions and receive assistance on breastfeeding-related issues, including information on the use of medicines and specialized medical procedures. The helpline operates daily from 9:00 to 14:00 and is staffed by experienced midwives and

pediatricians (ICH, 2023). In addition, healthcare professionals and mothers can contact alternative breastfeeding support helplines to seek information on the safety of medications during breastfeeding, including the breastfeeding department of the "breastfeeding-friendly" public hospital "Elena Venizelou" (Elena Venizelou, 2023). However, the Greek healthcare system is lacking a database with data on the compatibility of drugs during pregnancy and breastfeeding, an area which needs further development.

Guiding principles for healthcare professionals on medication administration

The guiding principles aim to help midwives and other healthcare professionals become aware of their professional responsibilities regarding the safe administration of medicines to breastfeeding mothers and allow them to consider the key aspects of medication administration.

Initially, midwives and other healthcare professionals involved in the administration of medicines to breastfeeding mothers, should inform the breastfeeding mother about the importance of the medication intake, its compatibility with breastfeeding, the possible side effects that may occur and about monitoring the newborn/infant for adverse reactions. Therefore, they should respect the mothers' right and autonomy to obtain informed consent and their right to refuse the medication by actively participating in the shared-decision making process (Tigka *et al.*, 2022a).

Midwives and other healthcare professionals are responsible for administering medication in their field of practice. Therefore, they should be kept up-to-date with the latest guidelines and research on the compatibility of medicines with breastfeeding and rely on evidence-based information. Furthermore, they are responsible for their own continuing education and professional development. Healthcare professionals should also be aware of the legislation regulating their practice. As far as midwives in Greece are concerned, according to Article 2 of Presidential Decree 351/1989 (Government Gazette 159/A/14-6-1989), they are entitled to prescribe medicines (vitamins, iron, antispasmodics, pethidine, medicines for uterine contraction and local anesthetics) (Tigka *et al.*, 2023). Given the narrow range of prescribing capacity of midwives in Greece and their wide and highly trained expertise in providing care to women and newborns, it is vital to expand their capabilities in the area of prescribing medicines. No data on Greek midwives' prescribing rates was available following a systematic literature review, a field which definitely requires further investigation. As for midwives' knowledge and attitudes towards e-prescribing, only one relevant Greek survey was found. In this study midwives employed in refugee migrant camps were recruited. Approximately 70% of midwives responded accurately to knowledge questions about medicines, while 97.7% suggested that migrant women

should undergo routine examinations during pregnancy and postpartum period. Midwives' preference to have access to e-prescribing services for medications and routine check-ups was significantly correlated with their knowledge and perceptions regarding prescribing ($p < 0.001$) (Papari, 2022). Additionally, healthcare professionals should be aware of the patient's current medication intake and history before administering new medications and consult other healthcare providers as well, e.g. pharmacists, about potential drug interactions (NMBI, 2020).

Midwives and other healthcare professionals should pay attention to the quality of practice and recognize the importance of monitoring the effectiveness of the medication they have administered. They should monitor patients to ensure that the desired outcome has been achieved or report to the pharmacovigilance authority any adverse reaction occurred. Additionally, they should create and maintain a trusting relationship with patients. Information about the patient and the medication administered is confidential, thus healthcare professionals should safeguard it. Furthermore, healthcare professionals should provide honest and accurate information and prompt guidance to patients and their families. If the need for the administered medicine involves healthcare providers of different specialities, the midwife should refer the breastfeeding mother to the appropriate physician but should supervise and communicate with the members of the multidisciplinary team (NMBI, 2020).

CONCLUSION

With the continuous introduction of new drugs that can be taken during lactation, the establishment of sustainable surveillance and pharmacovigilance systems becomes essential. Undoubtedly, the contribution of midwives and other healthcare professionals involved in breastfeeding plays a key role in the process of pharmacovigilance. Through the observation and reporting of adverse effects of medicines on breastfeeding women and their newborns/infants, and on women of childbearing age in general, midwives can contribute to a more rational and safer use of medicines. Therefore, it seems necessary to shift the focus towards providing information and education to midwives on pharmacovigilance at undergraduate and postgraduate level, so that more systematic reports can enrich the sources of information on drug compatibility during lactation with new data. Additionally, the development of alternative methods based on PBPK modeling is an important advancement in ensuring the safe use of drugs during lactation. Midwives and other healthcare professionals involved in the administration of medications to breastfeeding mothers should be aware of their professional responsibilities to safely prescribe medicines and be able to consider important aspects of medication administration. The ultimate goal is to support and prolong breastfeeding with evidence-based knowledge.

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