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**Titolo tesi:** Use of medications during breastfeeding: a multi-perspective approach

### **ABSTRACT**

**Background.** It is widely believed that many medications are dangerous for infants if taken by nursing mothers. So, they often choose to give up the drug in order to continue breastfeeding or, conversely, to discontinue breastfeeding to take the medication. This occurs even for medications considered as compatible by strong scientific evidence. The lack of coherent official information on the use of medications during lactation is probably one of the main reasons inducing an excess of prudence, based on presumption of risk rather than on evidence. In addition, literature suggests that breastfeeding training has a crucial role to increase healthcare professionals' knowledge, skills and attitudes and to improve professional support for breastfeeding. This applies also for the use of medications during breastfeeding.

**Objectives.** The objectives of this doctoral program are: (1) to assess the coherence and consistence of the sources of information on the use of medications during breastfeeding, (2) to explore opinions, attitudes and practices of the women about the use of medications during lactation, and (3) to assess the effectiveness of an e-learning training on breastfeeding (included the use of medications) in improving attitudes and self-declared practices of healthcare professionals.

**Methods.** Three different studies were carried out to test these doctoral objectives. First, we conducted a study to compare the information about the use of medications during breastfeeding. Information contents were retrieved by the Package Leaflets (PLs) and Summary of Product Characteristics (SPCs), Hale and Rowe's manual and the LactMed database. Second, a mixed-methods study with a sequential exploratory design was carried out. In the first qualitative phase, we conducted focus groups and in-depth interviews with mothers attending community services. On this basis, we built a questionnaire administered to pregnant women and new mothers. Third, we conducted a pre-post study, comparing healthcare professionals' attitudes and practices before and after an online course on breastfeeding.

**Results.** Regarding the information on the safety of the medications during lactation, the PLs and SPCs report a higher risk profile than the one expressed by Hale and Rowe's manual and the LactMed database and they often suggest the interruption of lactation even for compatible medications, sometimes defined inappropriately as "not recommended".

In cases of pharmacotherapy, women show three main attitudes: (1) to stop breastfeeding in order to take the medication, (2) to "endure the pain", or (3) to use natural products, perceived safer than drugs. Furthermore, women expressing an "endure the pain" opinion and women who considered natural products to be safer than medications had a higher probability of knowing that babies should be exclusively breastfed for the first 6 months (respectively, odds ratio [OR] = 2.24; 95% confidence interval [CI], 1.26-3.97; OR = 4.77; 95% CI, 2.56-8.88).

Finally, the online course on breastfeeding (N = 15004) improved healthcare professionals' attitudes, while minor changes were observed on practices ( $p < .05$ ). Considering each item, the main effects were observed on use of medications during breastfeeding ( $3.02 \pm 1.29$  at T0,  $1.88 \pm 1.08$  at T1).

**Conclusion.** In the dilemma of the mothers needing drug treatment, health professionals play a crucial role to provide individualized treatments, tailored to the single mother-baby case. To achieve this goal, health professionals need accurate and comprehensive information about medications, breastfeeding management and pharmacovigilance to



help their decision-making process. A non-interactive, high coverage e-learning approach seems a useful tool to improve awareness and positive attitude towards breastfeeding but also towards use of medications during lactation among the healthcare professionals.

On the basis of these findings, we hypothesize two line of development of the doctoral project. First, the building of a specific online training on use of medications during lactation, management of breastfeeding and pharmacovigilance for healthcare professionals. Second, follow-up studies in collaboration with an important Italian drug information service to explore mothers' practices after contacting this service.

Key words. Breastfeeding; medications; pharmacovigilance; attitudes; mothers; healthcare professionals.