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WOLFE L. University of North Texas, Denton, TX, Unites States. Quality Assurance Is Not Quality Control: Where Does OTIS/MotherToBaby Fit In?

In September of 2015, OTIS/MotherToBaby launched our texting program, adding an option for women to text our specialists. Our goal was to meet the overwhelming demand of women everywhere for a quick but accurate answer to their pregnancy and breastfeeding exposure questions. Texting would allow us to serve more people with fewer financial resources, and to better serve populations that our traditional phone and clinic based teratogen counselling services had previously not reached. These populations included pregnant teens, Hispanic and American Indian Women, and women in the lower social-economic classes. Along with developing and introducing our new texting program, we were faced with the huge task of developing quality assurance and quality control guidelines and protocols. Prior to the establishment of the MotherToBaby texting program, most of our affiliate teratogen services had acted independently within their own programs, some for the past 20 or 30 years. Suddenly we had multiple teratogen specialists from different services, all coming together and being expected to provide the same information to consumers and health care providers, every time, for every question! So how to develop a quality assurance program? And what is quality assurance (QA)? In researching this, we find that QA is process oriented, the way we manage quality. So, then what is quality control (QC)? QC is product oriented, the way we verify the quality of our output, in this case, the text messages that we are providing to consumers and HCP's. My talk will explore how OTIS went about developing our QA process and look at what level of success we have reached. Along the way, we had to look at our standards of performance, are we consistently providing both high quality and accurate information to all who use the texting program? Also, what type of client satisfaction tool are we using? Good QA and QC require evaluation, observation, feedback, and document review. Where does OTIS fit into all of this? What about our Live Chat and email services? Our daily phone counselling and in-clinic services? Does OTIS consistently meet the QA standards that we have set for ourselves?

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TE WINKEL B[1], VORSTENBOSCH S[1], VAN PUIJENBROEK E[1,2]. [1]Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, The Netherlands, [2]PharmacoTherapy, Epidemiology, and Economics, Groningen Research Institute of Pharmacy, University of Groningen, Groningen, The Netherlands. Teratogenicity of Second Generation Antiepileptic Drugs in EURAP Netherlands

Purpose: Women with epilepsy and their healthcare providers are faced with the difficulty in balancing the teratogenic risk resulting from seizures during pregnancy, against the potential risk of taking antiepileptic drugs to prevent these seizures. Older antiepileptic dugs, like valproate and carbamazepine, are known to be teratogenic. The teratogenic potential of the second- generation antiepileptic drugs, marketed since the 1990's, is still largely unknown. In this study, we report the results of first trimester exposure of lamotrigine, levetiracetam, oxcarbazepine and topiramate, assessing potential risks on pregnancy outcomes. Methods: The current study is a prospective observational cohort study. Data are collected in the Dutch part of an International Registry of Antiepileptic Drugs during Pregnancy (EURAP). 956 women taking antiepileptic drugs at conception were eligible for inclusion irrespective of the indication for treatment (epilepsy or other disorders). Using logistic regression analysis, we analyzed the prevalence of major congenital malformations (MCMs), until one year after birth and spontaneous abortions, after first trimester exposure to four second generation antiepileptic drugs (lamotrigine, levetiracetam, oxcarbazepine or topiramate) in comparison with carbamazepine monotherapy. Results: No statistically significant differences in the rate of major congenital malformations were found between monotherapy of second generation antiepileptic drugs and carbamazepine ("MCMs/total number of terminations with MCM, stillbirths and live births"; 12/297 lamotrigine, 7/121 levetiracetam, 2/51 oxcarbazepine, 0/15 topiramate and 13/204 carbamazepine). Regarding polytherapy, only the combination lamotrigine with valproate (6/30) showed a statistically significant increased risk on major congenital malformations compared to carbamazepine monotherapy, OR 3.15 (95% CI 1.11-8.96). Spontaneous abortions rates did not statistically significantly differ between the antiepileptic drugs, neither for mono- or polytherapy. Monotherapy "spontaneous abortion/pregnancies"; 21/316 lamotrigine, 16/133 levetiracetam, 6/56 oxcarbazepine, 1/16 topiramate and 24/225 carbamazepine. Conclusions: Our study revealed no additional potential teratogenic risks after first trimester exposure to the four second generation antiepileptic drugs. Knowledge of the teratogenic potential of second generation antiepileptic drugs other than lamotrigine is limited. Based on our results combined with previous findings, treatment may be continued with these antiepileptic drugs during pregnancy if epilepsy requires treatment and is well managed, even though we cannot rule out a potential teratogenic risk.