

Utilisation of smoking cessation pharmacotherapies during pregnancy: a multi-national population-based study.

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Introduction and aims: There are significant evidence gaps regarding the safety of smoking cessation pharmacotherapies when used during pregnancy, especially in relation to the risk of congenital malformations and other rare outcomes. Consequently, professional bodies advise against the use of varenicline and bupropion during pregnancy and recommend nicotine replacement therapy be used with caution. Despite the potential risks, it is unknown how many women use these medicines during pregnancy. This study will quantify, across four countries, the proportion of women using smoking cessation pharmacotherapies during pregnancy. We will also determine the extent of use during the first trimester specifically, the period of vulnerability for congenital malformations.

Method: All pregnancies that resulted in birth [live and stillbirths] in New South Wales (NSW), Australia, New Zealand, Norway, and Sweden between 2015-2020 have been identified from routinely collected data sources. These records were linked to pharmaceutical dispensing records. We will define use of a smoking cessation pharmacotherapy during pregnancy as having at least one dispensing with days' supply overlapping the period from date of conception to childbirth. Country-specific prevalence of exposure (any and each specific pharmacotherapy) will be calculated among all pregnancies and among pregnancies with maternal smoking. We will estimate the prevalence of use during the first trimester of pregnancy, defined as the 11 weeks following date of conception.

Results: Data analysis is underway. We expect to include 499,000 pregnancies in NSW, 355,000 in New Zealand, 333,000 in Norway and 578,000 in Sweden.

Implications for practice or policy: These results will indicate whether utilisation of smoking cessation pharmacotherapies in pregnancy align with current recommendations. The findings may inform interventions to improve the quality use of these medicines.

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