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Letter

## Malformations and pregnancy with schizophrenia

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The study highlighting the high prevalence of complications associated with pregnancy, delivery and neonatal outcomes (gestational diabetes, gestational hypertension, genito-urinary infection, intra-uterine growth retardation and preterm labour) in women with schizophrenia deserved comment [1].

The claim that “no significant differences were found for congenital malformations ( $p=0.18$ ) failed to raise adequate concern about a 23% increase in risk or absolute risk increase of 0.5%, (2.7% during pregnancy with schizophrenia vs 2.2% in controls) [1]. The role of antipsychotic medications should have been investigated as, for example, olanzapine causes major congenital malformations [2]. Sadly, antipsychotic prescriptions are not available in the French national hospital database. Further, this risk is likely to be underestimated as serious malformations can explain, at least in part, the 2.17 increase in the adjusted odds ratio for stillbirth and medical abortion [1]. Indeed, there is a two-fold higher risk of stillbirth in women exposed to antipsychotic medications compared with women exposed only prior to pregnancy [3]. Last, further investigations are needed to characterize child neurodevelopmental as effects of antipsychotic medications on the developing fetal brain are likely.

Fabre and colleagues rightly called for health policy interventions before and during pregnancy with social determinant approaches as well as for maintaining antipsychotic treatment at the lowest dose possible [1]. However, as the evidence base for psychotropic use in pregnancy is exclusively observational, it is not acceptable that the safety issue remains by-passed once more. Post-market surveillance studies must be systematic and mandatory [4,5]. In the era of ‘big

data’, data linkage between prescriptions with obstetric and child outcomes should be routine for drugs during pregnancy.

### Contributors

AB wrote the original draft, SB reviewed & edited. Both validated the final piece.

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### Declaration of Interests

AB and SB are among industry independent experts on Jeanne Lenzer's list (<https://jeannelenzer.com/list-independent-experts>). SB chairs Healthwatch, a charity promoting science and integrity in healthcare (<https://www.healthwatch-uk.org/>).

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