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The implementation of model-informed dose recommendations in pregnancy

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Objective

Standard dose recommendations do not take into account physiological changes in pregnant women's bodies, leading to a risk of maternal and/or fetal underdosing or overdosing. Pharmacokinetic models can help optimize dosing in pregnancy. We aimed to explore the willingness to use and preferred features for a model-informed pregnancy formulary (MIPF) among European healthcare practitioners (HCPs) and pregnant women.

Methods

A cross-sectional study was performed using two anonymous online surveys disseminated among HCPs and pregnant women across European countries. The two surveys were developed drawing on the findings from previous focus groups and interviews on the perceived barriers and facilitators for setting up a MIPF among HCPs and pregnant women in the Netherlands. Each survey consisted of statements associated with Likert scales. The surveys were available in English and in Dutch. The surveys were disseminated through open anonymous links shared with medical, midwifery and pharmaceutical societies as well as on websites and social media channels for pregnant women. Both surveys were active between 12 September and 30 November 2022. A descriptive analysis of the results was performed.

Results

In total, 610 HCPs and 808 pregnant women across 15 countries answered the surveys. Among HCPs, 56% worked in the Netherlands and 25% in Belgium. HCPs comprised 37% pharmac(olog)ists, 26% obstetricians, 11% midwives and 26% HCPs from other specialties. Among HCPs, 93% indicated that they would be willing to follow model-informed dose recommendations in pregnancy. HCPs would like to access information on the associated maternal and fetal risks and benefits (97%), on physiological changes and drug pharmacokinetics in pregnancy (91%) as well as recommendations on individual dose adjustments (97%) and on how to detect underdosing or toxicity (94%). Additionally, 88% of HCPs indicated they would like to access the evidence supporting pregnancy-adjusted doses. Among pregnant women, 49% of whom resided in the Netherlands and 32% in Belgium, 88% had used medication at least once during pregnancy. Most pregnant women wanted to understand why they may require an altered medication dose (96%) while 97% would like to be involved in decisions on medication doses by their HCP. Seventy-six percent of pregnant women appeared willing to follow dose recommendations informed by evidence from computer models.

Conclusion

The willingness to follow model-informed dose recommendations in pregnancy is high among HCPs and pregnant women. The surveys additionally shed light on the information needs of both groups of respondents as part of a MIPF.