EDITORIAL

Of course – but there's more to consider

In 2026, the inclusion of pregnant or breastfeeding women in clinical trials of drugs is portrayed as a necessary development, and perhaps even beyond debate (see p. 277 of this issue). For decades, these women have been excluded from the vast majority of trials. This exclusion has forced the healthcare decision-making process down a delicate path, wedged between the fear of another tragedy like the *thalidomide* or *diethylstilbestrol* (*DES*) disasters and the risk of depriving women of the potential benefit of an otherwise appropriate treatment.

Is it time, at long last, to find another way? Yes, of course. Another way is needed, one that enables us to better evaluate the harm-benefit balance of a substance, and to better document the adverse effects of drugs in the specific clinical situation of each pregnant or breastfeeding woman. One that enables us to obtain high-level evidence through rigorous comparative clinical trials versus first-choice treatments, and to share the relevant information with each patient, and perhaps with the other parent of the unborn child, so that those concerned can make informed decisions calmly.

Yes, of course – but there's more to consider: certain questions must be asked beforehand, in order to avoid unnecessary harm. Very often when a pregnant or breastfeeding woman takes a drug, both the mother and the child are exposed to that drug. There must therefore be compelling arguments that the study drug is highly likely to represent a tangible therapeutic advance. If efficacy has not been demonstrated in patients who are neither pregnant nor breastfeeding, there is no reason to expose mothers and their children to that drug.

The presence of an unborn or breastfeeding child reinforces the ethical imperative to conduct research aimed at developing treatments that represent an advance for patients, rather than research aimed simply at generating data or obtaining marketing authorisation. In other words, in trials that include pregnant or breastfeeding women, there is an even greater need than usual for the comparator to be the first-choice treatment for these women, and for robust methodology capable of producing high-level evidence.

And as always, before prescribing or recommending a drug to a pregnant or breastfeeding woman, it is useful to first consider a few points. Is the clinical situation in question a benign condition that resolves spontaneously or for which treatment can safely be delayed? What are the foreseeable adverse effects, including long-term adverse effects, in light of what is known about the drug, and about its teratogenicity or fetotoxicity in animals? All this, while bearing in mind that clinical trials seldom detect those adverse effects that are rare but serious, and that pharmacovigilance therefore remains essential.

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