Doubling of deaths among sick mums-to-be amid poor evidence on drug safety in pregnancy

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The lack of hard data on the safety and effectiveness of a wide range of drugs in pregnancy has hindered the treatment of pregnant women, contributing to a doubling of deaths amongst mums-to-be with an underlying health problem over the past 20 years, argues an editorial in the *Drug and Therapeutics Bulletin* (*DTB*).

It's time to include pregnant women in drug trials so that they can get the medical treatment they need, says *DTB*.

In the absence of reliable information on the pros and cons of treatment during pregnancy, and haunted by the spectre of thalidomide, doctors are reluctant to prescribe, while pregnant women are wary of taking drugs that might harm their developing baby, contends the editorial.

Yet an estimated one in 10 mums-to-be has a long term condition that requires medication, while around four out of 10 develop new health problems during their pregnancy.

And it's going to get worse, prompted by the increasing trend for older age at childbirth and the expanding girth of the nation, both of which are pushing up the numbers of women requiring drug treatment during their pregnancy, warns the editorial.

Some 4% of women who gave birth in England and Wales in 2011 were

aged 40 and over—compared with just 1% a decade earlier—while almost one in five women of childbearing age were obese in 2008.

But the unwillingness to prescribe and be treated can be fatal, warns *DTB*. The number of "indirect" deaths among new mums in the UK - where pregnancy worsens a new or pre-existing medical or mental health problem - has almost doubled over the past 20 years, and now exceeds deaths directly caused by pregnancy by 50%, it says.

It's rare for a drug company or research team to include pregnant women in drug trials, says *DTB*. All too often they are put off by the complex ethical issues involved.

Yet equally, it could be argued that it is unethical not to include them in drug trials, especially as side effects can take many years to emerge, it says, citing sodium valproate, the anti-epileptic drug, as a case in point.

["This] was hailed as a wonder anticonvulsant in the 1960s, linked with neural tube defects in the 1980s, and associated with adverse neurodevelopmental effects in the offspring with third trimester exposure in the 2000s," it notes.

It's time to emulate the way in which children's medicines are now being investigated properly, says *DTB*, which calls on industry and regulators to include women in drug trials.

"With increasing awareness that the intrauterine environment is important for the long term development of children, it is ever more important that those involved in drug development and trials look for ways to safely involved pregnant women rather than automatically exclude them," contends the editorial.

"Pregnancy is a natural state that has been ignored by the pharmaceutical

industry for too long," it concludes.

More information:
www.dtb.bmj.com/lookup/doi/10.1136/dtb.2013.6.0182

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