

RCOG SIP paper on obstetric drug development

Key messages

- There is an urgent need for the development of new drugs for use in obstetrics. This RCOG Scientific Impact Paper (SIP) addresses the reasons for this and suggests ways that barriers to finding new treatments could be overcome.
- A mother needs to be properly informed so that she can weigh up the potential risks to her and her baby of taking or not taking any medication during pregnancy or when breastfeeding.
- Strategies to improve the development of new obstetric treatments are recommended in the paper:
 1. Identifying drugs to treat obstetric conditions that are already licensed for treatment of disease outside pregnancy.
 2. Supporting research to test drugs using human tissue.
 3. Finding more accurate ways of diagnosing obstetric conditions early and supporting the conduct of high quality clinical trials.
 4. Changing current regulatory pathways to find new ways to combat issues with litigation and indemnity, and reduce the currently excessive costs.
 5. Establishing a database of the use of drugs used during pregnancy to monitor their safety, effectiveness, and their long term outcomes on child development.
 6. Evaluating the suitability of all drugs in development for use in pregnancy.
 7. Encouraging pharmaceutical companies to spend the time and money investigating and licensing drugs in pregnancy.
 8. Involving patients in determining how risks are assessed, and what risks they consider to be acceptable.

Q&A

Why should pharmaceutical companies invest in developing obstetric drugs?

Maternal and perinatal disease counts for approximately 7% of global disease, yet of all the treatments in research and development, only 1-5% are designed to help new mothers and pregnant women.

There is currently a lack of new drug development and a database from 2007 found that there were 1636 drugs under development for neurological conditions but only 17 for maternal health conditions.

What are the challenges in developing obstetric drugs?

The challenges of developing obstetric drugs include high development costs, difficulties in trial design, complex ethical and regulatory issues and a lack of suitable animal models in which to test new drugs.

How common is the use of medication in pregnancy?

Medication during pregnancy is very common, with 80% of pregnant women having at least one prescribed drug either as a continuation of a pre-existing treatment or for pregnancy-associated problems.

What are the risks of taking medication during pregnancy?

The main concern medication use in pregnancy is the possibility of problems with the baby's development in the womb.

For many women the potential harm of taking a drug that may risk the health of the unborn child, must be weighed against the health risk to both the mother and the baby of not taking the medication. Decisions must be made alongside advice from a healthcare professional.

If I am taking a drug before I fall pregnant, such as anti-epilepsy medication, what should I do?

Consult your GP, obstetrician or midwife if you are trying to conceive or are pregnant. They will provide advice and support to help ensure the best care is provided for you and your baby.

Can I breastfeed if I have been taking medication during pregnancy and after the birth?

There can be a risk that a medication can transfer into a mother's breast milk. Speak to your GP, obstetrician or midwife for advice on breastfeeding.

Are drugs which are not licensed for use during pregnancy safe?

A licensed drug has satisfied the regulatory authorities that it has undergone a rigorous evaluation of efficacy and safety. A license is expensive and often governed by commercial reasons.

Certain medications which are not licenced for use in pregnancy are used by clinicians to treat various conditions during pregnancy. An example is misoprostol, although it is not licensed for use for reproductive health indications, it is on the World Health Organisation Model List of Essential Medicines for prevention of heavy bleeding following birth.

Doctors sometimes choose an unlicensed product for use in pregnancy, even when a licensed alternative is available. The paper recommends reducing the costs associated with meeting licensing requirements.

Where do I find more information?

Speak to your GP, midwife or obstetrician. Information from other sources, such as certain internet sites may be incorrect.

Additional information

NHS Choices information on medicines and pregnancy: <http://www.nhs.uk/conditions/pregnancy-and-baby/Pages/medicines-in-pregnancy.aspx>

NHS Choices information on the licensing of medicines:
<http://www.nhs.uk/Conditions/Medicinesinfo/Pages/Safetyissues.aspx>

NHS Choices information on clinical trials and medical research:
<http://www.nhs.uk/Conditions/Clinical-trials/Pages/Phasesoftrials.aspx>

NHS Choices on the safety and regulation of medicines:
<http://www.nhs.uk/Conditions/Medicinesinfo/Pages/MHRA.aspx>

Bumps, a charity dedicated to the best use of medicines in pregnancy:
<http://www.medicinesinpregnancy.org/>