

Challenges of developing obstetric medicines discussed in scientific opinion paper

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The development of new drugs for use in obstetrics is long overdue. A Scientific Impact Paper (SIP) published today (13 May) by the Royal College of Obstetricians and Gynaecologists (RCOG) addresses the reasons for this and suggests ways that barriers to finding new treatments could be overcome.

SIPs are produced by the Scientific Advisory Committee at the RCOG and are up-to-date reviews of emerging or controversial scientific issues of relevance to [obstetrics](#) and [gynaecology](#).

Maternal and perinatal disease counts for approximately 7% of global disease, yet fewer than 5% of the number of drugs being developed to combat cardiovascular disease are designed to help new mothers and [pregnant women](#).

The paper highlights that, despite the obvious demand and the challenges to obstetric [drug](#) development, more should be done to help mothers and babies. These challenges 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](#).

The paper outlines strategies to improve the development of new obstetric treatments.

1. Identifying drugs to treat obstetric conditions that are already licenced for treatment of disease outside of pregnancy. The

safety profile of such drugs is already mostly known which may shorten the time to clinical use.

2. Supporting research to test drugs using human tissue, such as placenta, samples after pregnancy termination, and breast milk.
3. Finding more accurate ways of diagnosing obstetric conditions to help identify women sooner who would benefit from treatment, and aid in the conduct of high quality clinical trials.
4. Encouraging research and development by changing current regulatory pathways, for example the academic community, regulators, pharmaceutical industry and the Government need to collaborate to find new ways to combat issues with litigation and indemnity, and so reduce the currently excessive costs.
5. Establishing a database of the use of drugs used during pregnancy (whether licenced or not) 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 to avoid leaving pregnant mothers uncertain about their safety.
7. Preferentially using licenced drugs for an obstetric condition, when available, in order to encourage 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.

Dr Anna David, Consultant Obstetrician at UCL Hospitals, and lead author of the paper said:

"The consequences of obstetric diseases have a huge effect on the quality of life for individuals and their carers. They also have financial impact requiring extensive educational, social and health input for affected children.

"More investment in the development of obstetric medicines is needed to give pregnant women and their babies the level of healthcare they deserve. All healthcare professionals who care for pregnant women should be involved in the common aim of developing new treatments, ensuring that patients have the opportunity to take part in clinical trials and to witness the implementation of research findings into clinical practice."

Dr Sadaf Ghaem-Maghani, Chair of the RCOG's Scientific Advisory Committee, said:

"One of the main concerns is the possible damaging effect of drugs to babies during development. 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.

"There is a real need for an improvement in the treatments available for obstetric conditions. The strategies outlined by the RCOG are designed to encourage pharmaceutical companies to invest in drugs to treat pregnant and new mothers, while sharing information will make drug choices easier for both doctors and their patients."

Provided by Wiley

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