BRITISH JOURNAL OF HOSPITAL MEDICINE

Fear of using medicines in pregnancy risks the lives of women and children

Medicine research and development has been instrumental in improving outcomes for countless individuals, but women, especially pregnant women, have been left behind. Disadvantaged during pregnancy as a result of apprehension over drug use for new or existing conditions, women face worse outcomes for under- or untreated disease. Solving this problem will require input from regulators, the pharmaceutical industry and clinicians.

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Obstetricians frequently say 'pregnancy is not a disease' to normalise a process that, for many women progresses successfully, without intervention. However, maternal and perinatal mortality remains a problem of varying degrees across the world. Many of these deaths are preventable, often relating to existing conditions exacerbated by pregnancy or new disease that develops during pregnancy.

While maternal mortality rates in the UK are low, undertreated or untreated conditions in pregnancy still result in unnecessary maternal and perinatal morbidity and mortality. Every year in the UK, 5000 infants experience a perinatal death, and 70 women die as a result of pregnancy-specific conditions (Bhattacharya et al, 2021). While the number of women with medical conditions in pregnancy that require treatment continues to rise, clinicians' ability to provide safe, timely and quality treatment is severely hampered by the lack of new medications. Only two new medications have been approved for use in pregnancy in the last 40 years (Concept Foundation, 2022). The barriers cited include concerns regarding the potential effects on a developing fetus – irrespective of the stage of development – and the financial and legal risks involved when extending licenses for established medications for use in pregnancy.

When concerns regarding actual or theoretical pregnancy during women's reproductive years are given precedence over the health of the individual concerned, this risks not only the health of the woman, but also the healthy development of her children as well as wider society. This approach can have significant societal and economic implications. Stillbirth has a significant negative psychological impact on a woman and her family, which can inflict lifelong social and economic harm. Preterm birth in England and Wales has been estimated to cost the UK economy £2.9 billion each year, including the long-term costs of disability which occurs in over 25% of these births (Mangham et al, 2009). Poor health in women, especially during pregnancy, can mean perpetuate health inequalities for generations.

'Healthy Mum, Healthy Baby, Healthy Future', a policy commission report on the availability of safe, effective and accessible medicines for use in pregnancy, was published in conjunction with Birmingham Health Partners in May 2022 (Bhattacharya et al, 2022). The report gathered evidence from expert witnesses across a range of sectors, to understand the barriers limiting medicine use in pregnancy. The evidence was far reaching, with recommendations advocating a multicollaborative stakeholder approach, which should underpin the UK government's 'Women's Health Strategy for England', published in August 2022 (Department of Health and Social Care, 2022).

While some recommendations are specific to sectors outside of clinical medicine, such as the pharmaceutical industry and health data agencies, many are directly relevant to clinicians in the NHS and those delivering care to women at any stage of life. Awareness of these recommendations is vital to positively influencing individual and population health outcomes.

Better understanding of use of existing medicines

There are many situations when disease control in pregnancy is suboptimal, as a result of confusion or concern regarding drug safety, and yet years of evidence on the safe

How to cite this article:
Ekechi C. Fear of using medicines in pregnancy risks the lives of women and children. Br J Hosp Med. 2022. https://doi.org/10.12968/hmed.2022.0312

'off-label' use of many generic medications is not shared, rendering current advice that these should not be used in pregnancy out of date and leaving some clinicians wary.

The recommendation to prioritise updates on existing drugs with the potential to be used safely in pregnancy could remove this unnecessary frustration. Allowing clinicians to share data on safe and effective use of medicines in pregnancy, and providing prescribing guides with updated, cautionary but safe prescribing guidelines, would enable flexible and effective clinical decision making.

The establishment of a designated maternity 'health data research hub' with a focus on collating evidence and experience of medicine use in pregnancy will improve understanding and increase confidence to use these treatments for women who need them. Input from all who manage medical conditions in pregnancy as well as those caring for women and their babies post-delivery will improve identification of medium- and long-term benefits and possible complications, in addition to benefits and complications that may occur in the immediate aftermath of their use.

Increased research with appropriate levels of caution

It is recommended that all research and development trials of new medications that may be used for women, during or outside of pregnancy should consider their potential use in women who may be or are pregnant, requiring the careful and considered inclusion of reproductive age and pregnant women. Concerns regarding litigation from harm caused by medical drug trials has resulted in a punitive insurance process that hinders medicine development. An insurance process which is safe for women but allows for wider research in pregnancy is required to support the inclusion of women and pregnant women in drug trials.

The thalidomide scandal that resulted in unintended negative fetal and neonatal outcomes from poorly evaluated medicines remains a significant concern for researchers, insurers and the public. No one wants a repeat of the devastating outcomes seen in the 1950s, but the conditions for testing new medicines have evolved significantly with increased pharmacovigilance and greater public awareness. It is vital that these improvements in safety are harnessed to allow women access to medicines that can improve the health of mothers and children.

Caution is necessary, but over-caution limits clinicians' ability to provide effective care. Increased caution unfairly places the assessment of risk and the burden of decision making on the woman. With minimal data, the decision-making process is over-simplified with the frequent conclusion that the theoretical risk of potential harm to the fetus, no matter how small, is of greater concern than the real and present risk of harm to the mother. The consequences of this can be disastrous.

There is no better example of this than what can be learned from the initial exclusion of pregnant women from the COVID-19 vaccination trials. Without trial data for pregnant women, the safety and effectiveness of the vaccines could not be assured. Despite real-world data confirming vaccine safety, women and clinicians alike remained wary. The result? At the height of the pandemic, 1 in 5 of the most critically ill patients in hospital with COVID-19 were pregnant unvaccinated women (NHS England, 2021).

Reducing maternal inequality

Including pregnant women in more research trials would provide more information and reduce the risk of litigation, the risk of unintended effects on the fetus and the risk of undertreated conditions in pregnancy. With three out of four women taking some form of medication during pregnancy, and as more pregnancies become more medically complex, it is increasingly likely that pregnant women will have one or more underlying health conditions that require treatment. Women with complex medical conditions often have other risk factors that put them at greater risk of maternal mortality and morbidity, and reluctance or an inability to treat their conditions further entrenches the widening inequality in maternal outcomes. With such a complex pregnant population, the fact that only 2% of the 3311 clinical studies currently being led at the University of Oxford involve pregnancy, as an example, is no longer acceptable (Bhattacharya et al, 2022).

Key points

- Shared knowledge of medicines that are safe for use in pregnancy is vital to increase patient and clinician confidence in treating medical conditions in these patients.
- Priority should be given to the inclusion of women who are pregnant or of reproductive age into research and drug development trials where they stand to benefit from their use.
- Inequality in maternal outcomes will only be reduced when conditions that complicate pregnancy are treated with the same urgency as in the non-pregnant population.

The knowledge gap regarding the use of medicine in pregnancy remains, yet research exists that is not shared among clinicians or with the public. That is why the recommendation for a coalition of pregnancy and baby charities, working alongside the public, academic and industry researchers and government, to create a shared vision for safe medicines evaluation and development in pregnancy, is key. Only this combined approach can achieve the clear and consistent advice needed by clinicians and the public.

Conclusions

It is time that women take the lead in key decisions regarding their own health, leaving behind the paternalistic approach. Awareness is key and clinicians caring for women should provide a unified voice on the need to prioritise the care of women in pregnancy and beyond. Women deserve clear information in order to make the right decisions for themselves. Researching and developing medical treatments or treating medical conditions in pregnancy must involve and include women at all levels. Only in this way can we ensure that women and their children receive the best chance of a healthy life, and that no mother or baby experiences a preventable death through a lack of treatment.

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References

Bhattacharya S, on behalf of Birmingham Health Partners Centre for Regulatory Science and Innovation. Safe and effective medicines for use in pregnancy: a call to action. 2021. https://www.birminghamhealthpartners.co.uk/wp-content/uploads/2021/01/21560-Policy-Commission-Maternal-Health-Report-AW-accessible.pdf (accessed 30 September 2022)

Bhattacharya S, on behalf of Birmingham Health Partners. Healthy mum, healthy baby, healthy future: the case for UK leadership in the development of safe, effective and accessible medicines for use in pregnancy. 2022. https://www.birminghamhealthpartners.co.uk/wp-content/uploads/2022/05/Final-Healthy-Mum-Healthy-Baby-Healthy-Future-Report-AW_Accessible-PDF-REDUCED-FILE-SIZE.pdf (accessed 30 September 2022)

Concept Foundation. Concept Foundation launches #ONLYTWODRUGSEVER. 2022. https://www.conceptfoundation.org/global-news/concept-foundation-launches-onlytwodrugsever/ (accessed 10 October 2022)

Department of Health and Social Care. Women's Health Strategy for England. 2022. https://www.gov.uk/government/publications/womens-health-strategy-for-england/womens-health-strategy-for-england (accessed 30 September 2022)

Mangham LJ, Petrou S, Doyle LW, Draper ES, Marlow N. The cost of preterm birth throughout childhood in England and Wales. Pediatrics. 2009;123(2):e312–e327. https://doi.org/10.1542/peds.2008-1827

NHS England. NHS encourages pregnant women to get COVID-19 vaccine. 2021. https://www.england.nhs.uk/2021/10/nhs-encourages-pregnant-women-to-get-covid-19-vaccine/ (accessed 30 September 2022)