

## Weighing benefits and costs of azithromycin during delivery

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Some infants of lactating mothers given the antibiotic and antimalarial, azithromycin, during delivery may be protected from disease, or harmed by the drug. These findings are the results of the most comprehensive evaluation of the transfer of azithromycin into breast milk to date. "Young infants cannot metabolize medicines as well as older children or adults and so even relatively small amounts absorbed from breast milk may produce effects, both therapeutic and adverse, in some suckling infants," explained corresponding author Timothy Davis, MB, D. Phil. The research is published in *Antimicrobial Agents and Chemotherapy*, a journal of the American Society for Microbiology.

In parts of the world such as Africa, women may be given <u>azithromycin</u> during delivery, both to protect the mother from becoming infected, and to protect <u>infants</u> from acquiring infections including chlamydia, gonorrhea, and ureaplasma via transmission from the birth canal during delivery, said Davis, who is Professor of Medicine, School of Medicine and Pharmacology, University of Western Australia, Fremantle Hospital, Perth, Australia. Additionally, in <u>breast milk</u> the drug may protect infants from acquiring infections such as pertussis, post-partum.

The risk for infants from azithromycin is a condition called <u>pyloric</u> <u>stenosis</u>. This is a narrowing of the outflow pipe from the stomach into the intestines. The first symptom is vomiting, which may progress to projectile vomiting, a particularly violent form. Babies with pyloric stenosis fail to gain weight, and may even lose weight. They also may become dehydrated.



In the study, the investigators took four breast milk samples over a period of 28 days, from each of 20 lactating women in The Gambia, an African country, to whom a single therapeutic dose of azithromycin had been given during labor. They measured the concentration of azithromycin in each sample of breast milk. They then used a mathematical model to predict how much of the drug the infant would absorb with continued breastfeeding, and compared this to recommended dose regimens for azithromycin used to treat bacterial infections in infants. That dose may exceed the conventional safety limit, said Davis.

"We found that there may be a reduced risk of bacterial infections in a minority of infants, but that some infants could develop pyloric stenosis as a result of breastfeeding in this situation," said Davis. Based on the predicted amount of drug absorbed, and epidemiologic data, the investigators estimated that in a worst-case scenario, there would be one case of pyloric stenosis for every 60 infants. "The real number is very likely to be less than this, especially as the background rate of pyloric stenosis appears relatively low in malaria-endemic tropical countries," said Davis. "Since our predictions are based on mathematical modeling and not real-life data, further larger-scale trials are needed to quantify these anticipated risks and benefits with greater precision."

**More information:** Sam Salman et al. Pharmacokinetics of transfer of azithromycin into the breast milk of African mothers, *Antimicrobial Agents and Chemotherapy* (2015). DOI: 10.1128/AAC.02668-15

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