Administering additional antibiotic prior to C-section reduces infection rates by 50 percent

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Physicians at the University of Alabama at Birmingham and colleagues have discovered that administering the antibiotic azithromycin alongside the standard recommended antibiotic regimen, cefazolin, reduces infection rates by 50 percent for women who have a non-elective cesarean delivery.

A study published in the *New England Journal of Medicine* shows adding the dose of 500 milligrams of azithromycin during a C-section also significantly decreases the use of health care resources, including readmissions, emergency room visits and clinic visits.

"Infection during pregnancy and during the postpregnancy period is a major health problem for both mom and baby, and a common underlying cause of death," said Alan T. N. Tita, M.D., Ph.D.; professor in the UAB Division of Maternal-Fetal Medicine and the Center for Women's Reproductive Health, and principal investigator of the study. "Women who have a C-section are at significantly increased risk for infection compared to those who deliver vaginally. A major national goal is to reduce the risk of infection after surgery, and this finding is the culmination of investigative work over decades."

Infection is among the top five causes of maternal death in the United States, and cesarean delivery is the most common major surgical procedure, with up to five times the risk for infection than a vaginal

delivery.

"When our group first developed the idea that a second antibiotic could help reduce infections for these women, we found reassurance in the fact that some patients who have preterm premature rupture of the membranes receive two antibiotics to help reduce infection and prolong pregnancy," Tita said.

A clinical trial funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development was conducted across 14 hospitals in the United States with 2,013 women who were more than 24 weeks' gestation and undergoing a C-section during labor or after membrane rupture. A randomized group of patients received either the standard antibiotic regimen to prevent infection or a modified regimen with the additional azithromycin. Pfizer Inc. donated the azithromycin and had no other role in the study.

"These results are extremely important, given that the maternal death rate has increased in the U.S. and there is an urgent need for therapies to decrease serious complications that can lead to maternal deaths," said Uma Reddy, M.D., NICHD project officer for the study.

The UAB Department of Biostatistics analyzed data gathered from 14 participating hospitals to reveal that the frequency of endometritis, an infection of the lining of the uterus, and infection of the cesarean wound were decreased by 50 percent in the women who received the adjunctive azithromycin compared to women who received the standard single antibiotic. The babies who were delivered with the additional azithromycin did not have an increased risk of adverse events.

"Further analyses indicate that the benefits associated with adjunctive azithromycin are consistent across several subgroups of patients," said Jeff Szychowski, Ph.D., associate professor in the UAB School of Public

Health Department f Biostatistics. "Thanks to the dedication of research staff across the consortium of 14 centers to successfully execute a clinical trial of this magnitude, we are poised to perform multiple follow-up investigations and to understand the ramifications of these results more completely."Additionally, hospital readmission rates and unscheduled visits to a clinic or to the emergency room were reduced.

"There are significant costs associated with infections," Tita said. "The reduction in readmissions, visits, fevers and overall antibiotic use due to the intervention was higher than we expected, and translates to reduced health care costs."

"This was a significant breakthrough that has identified a simple and inexpensive way to reduce the most common complication associated with cesarean delivery," said William Andrews, Ph.D., M.D., chair of the UAB Department of OB/GYN and chair of the Steering Committee for the study.

Provided by University of Alabama at Birmingham