

Research leads to pediatric labeling updates for doxycycline, clindamycin and caffeine citrate

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Drug labels for doxycycline, [clindamycin](#) and caffeine citrate now include better information for healthcare providers on recommended usage and dosage in pediatric populations. The data that informed these label changes came from research funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health.

"Doctors routinely make off-label drug decisions when treating infants and children because many drugs do not have pediatric safety or [dosage recommendations](#)," said Perdita Taylor-Zapata, M.D., program lead for the Best Pharmaceuticals for Children Act (BPCA) at NICHD. "The BPCA program supports research to improve the information on labels so that [healthcare providers](#) have clear guidance on how to prescribe drugs for their youngest patients."

Doxycycline is an antibiotic used to treat life-threatening [infectious diseases](#), including Rocky

Mountain spotted fever and anthrax. The revised drug label now includes weight-based dosing recommendations for treating serious diseases that currently have no alternative therapies for children two to eight years of age. The new recommendations apply to oral and intravenous forms of the drug.

Clindamycin is prescribed to treat various infections in children, including [lower respiratory tract infections](#), intra-abdominal infections, sepsis (infection in the blood), and bone and joint infections. The revised drug label updates weight-based dosing information for oral and intravenous forms of the drug.

Caffeine citrate is prescribed to treat apnea of prematurity, a breathing disorder that occurs in premature infants. The medication is commonly used off-label for infants born earlier than 28 weeks of pregnancy even though the previous label only offered guidance for infants born 28 to 32 weeks of pregnancy (a full-term pregnancy is 39 weeks). The revised label indicates that the drug may safely be given to preterm infants born earlier than 28 weeks, and the dose and duration may be higher and longer than what the previous label recommended. Data for this label change was also supported by a [clinical study, Prematurity and Respiratory Outcomes Program](#), funded by NIH's National Heart, Lung, and Blood Institute.

The NICHD BPCA program supports the Pediatric Trials Network (PTN), which studies drugs and therapies commonly prescribed for infants and children but never specifically tested in them. Results from these studies may inform an update to the [drug's](#) label by the U.S. Food and Drug Administration. PTN data for doxycycline, clindamycin and [caffeine citrate](#) are available online. [Revised FDA drug labels](#) are also available.

Provided by National Institutes of Health

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