

Prescription drug labels provide scant dosing guidance for obese kids

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Janelle D. Vaughns, M.D., director of bariatric anesthesia at Children's National and the lead study author. Credit: Children's National Health System

Despite the U.S. Congress providing incentives to drug manufacturers to encourage the study of medications in children, few approved drugs

include safe dosing information for obese kids.

A study conducted at Children's National Health System in conjunction with the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research surveyed pediatric medical and [clinical pharmacology](#) reviews under the FDA Amendments Act of 2007 and the FDA Safety and Innovation Act of 2012. The study used search terms related to weight and size to determine the current incorporation of obesity as a covariate in pediatric drug development.

Of the 89 product labels identified, none provided dosing information related to obesity. The effect of [body mass index](#) on drug pharmacokinetics was mentioned in only four labels, according to the study "Obesity and Pediatric Drug Development," published online Jan. 19, 2018, in *The Journal of Clinical Pharmacology*.

Data from the Centers for Disease Control and Prevention indicate that one in six children and adolescents in the U.S. is obese. Obesity increases the percentage of fat tissue more than it boosts the percentage of lean body mass and enlarges kidney size, factors that impact how the body takes up medicine, where it retains it and how quickly it is excreted.

"We are making progress in expanding the number of medicines with pediatric labeling, but we need to do more concerning providing dosing guidelines for children with obesity," says Janelle D. Vaughns, M.D., director of bariatric anesthesia at Children's National and the lead study author. "Moving forward, regulators, clinicians and the pharmaceutical industry should consider enrolling more [obese patients](#) in pediatric clinical trials to facilitate the safe and effective use of the next generation of medicines by [obese children](#) and adolescents."

Provided by Children's National Medical Center

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