

Off-label medication orders on the rise for children, study finds

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U.S. physicians are increasingly ordering medications for children for conditions that are not approved by the Food and Drug Administration, according to a Rutgers study.

The findings highlight the need for more education, research and policies addressing effective, safe pediatric drug prescribing.

The study, published in the journal *Pediatrics*, analyzed data collected from 2006 to 2015 in the Centers for Disease Control and Prevention's National Ambulatory Medical Care Surveys, which provide information on doctor office visits across the U.S. The researchers analyzed the frequency, trends and reasons why doctors ordered unapproved medications for [children](#) under 18.

It is the first study in a decade to look at how U.S. doctors outside of hospitals order a broad range of medicines off-label to children. This study focused on systemic drugs, which work throughout the body and have a greater potential for toxicity.

Many drugs prescribed for children [have not been rigorously tested in children](#), according to the Food and Drug Administration. "Off-label medications—meaning medications used in a manner not specified in the FDA's approved packaging label—are legal. We found that they are common and increasing in children rather than decreasing," said senior author Daniel Horton, assistant professor of pediatrics and a pediatric rheumatologist at Rutgers Robert Wood Johnson Medical School. "However, we don't always understand how off-label medications will affect children, who don't always respond to medications as adults do. They may not respond as desired to these drugs and could experience [harmful effects](#)."

The study found, for about 19 percent of the estimated two billion office visits for children studied, doctors ordered one or more off-label systemic drugs, often for common conditions such as respiratory infections, asthma or mental health disorders. In visits with at least one drug order, doctors ordered drugs off-label in about 83 percent of newborn visits, 49 percent of infant visits and about 40 percent of visits

for other ages. The study also found that, among visits with at least one ordered drug, the rates of ordering off-label increased from 42 percent in 2006 to 47 percent by 2015.

Rates of off-label [drug](#) orders were higher for girls and for children with chronic conditions. Physicians in southern states ordered off-label drugs more often than physicians in other regions of the country. Specialists ordered them more commonly than general practitioners.

The most frequently ordered off-label drugs were antihistamines for respiratory infections, several classes of antibiotics for respiratory infections and antidepressants for attention-deficit/hyperactivity disorder.

"Despite the laws in this country and Europe that encourage and require research on medications for children, we found that physicians are increasingly ordering certain medications off-label for children," said Horton.

"Use of some off-label drugs is supported by high-quality evidence. For example, drugs approved to prevent vomiting caused by chemotherapy also work quite well in treating more common causes of vomiting in children, such as from viruses. We need this kind of evidence to determine the appropriateness of use of many other drugs currently used off-label to treat a wide range of conditions in children," Horton said.

More information: *Pediatrics* (2019). [DOI: 10.1542/peds.2019-0896](https://doi.org/10.1542/peds.2019-0896)

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