

# Off-label medications prescribed to nearly all pediatric intensive care patients

October 21 2012

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"Off label" drugs are medications that have not been tested for safety or efficacy for a specific patient age or condition. New research presented Oct. 21 at the American Academy of Pediatrics (AAP) National Conference and Exhibition in New Orleans found that off-label treatments were ordered for 96 percent of all pediatric patients, and 100 percent of patients ages 13-17, in the intensive care unit of an urban children's hospital.

In "Off-Label [Drug Use](#) in the [Pediatric Intensive Care](#) Unit," researchers collected data on all patients admitted to the 32-bed pediatric [intensive care unit](#) (PICU) at Primary Children's Medical Center (PCMC) in [Salt Lake City](#) from October 2002 to February 2003, including age, diagnosis, medications ordered and indication for each medication ordered. Each drug was assessed for whether it was used in an on-label or off-label manner.

Off-label use was declared when a drug was prescribed for a patient whose age was not listed on the package label, no pharmacokinetic (PK) data was listed in the package insert, and/or if the drug was used for a non-FDA approved indication.

A total of 335 drugs were prescribed in 492 [pediatric patients](#) from birth to age 17. Ninety-six percent of patients received at least one off-label drug. Off-label prescribing occurs in almost every patient in the PICU.

"Treatment with off-label medications is the rule rather than the

exception in the PICU," said study author Susan Sorenson, a doctor of pharmacy.

"Numerous problems emanate from the lack of drug data in children, including uncertainty about whether a drug is effective in children for a particular disease, questions about the side effect profile, and lack of dosing information," said Dr. Sorenson.

"It is very difficult when you stand at the bedside and want to treat a sick child with a drug and you don't know if the dose or drug you have chosen or recommended will harm the child or help the child. Everyone does the best they can to find suggested doses and do the right thing, however, it is better medicine to dose or recommend doses based on evidence.

"This study is attempting to determine the drugs that are used most frequently in our sickest patient population that do not carry dosing information, with the intent that studies of dosing, safety, and efficacy will be carried out on those drugs," said Dr. Sorenson. "More studies need to be conducted so that prescribing in our youngest and sickest patients can be done based on evidence."

Provided by American Academy of Pediatrics

Citation: Off-label medications prescribed to nearly all pediatric intensive care patients (2012, October 21) retrieved 24 February 2024 from <https://medicalxpress.com/news/2012-10-off-label-medications-pediatric-intensive-patients.html>

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