Only half of meds taken by kids have 'adequate' safety info: study

May 11 2012, By Jenifer Goodwin, HealthDay Reporter

Medications used in newborns especially under-studied, doctor says.

(HealthDay) -- About half of medications used in children have little or no label information about drug effectiveness, safety or dosing in children, new research finds.

"We still have a long way to go," said senior study author Dr. M. Dianne Murphy, director of the U.S. Food and Drug Administration's Office of Pediatric Therapeutics, although she acknowledged significant strides in pediatric labeling over the past few decades.

In the study, when the researchers looked at 560 medications listed in the 2009 electronic Physicians' Desk Reference, some not relevant for pediatric use, they found only 46 percent referred to children's usage. When they looked only at drugs used in children, they found "adequate"

labeling information for 231 of 461 drugs. "Adequate" meant they included information on drug effectiveness, safety in kids and teens, and guidance on dosing.

Among medical professionals, there's a growing understanding that children aren't mini-adults. They may metabolize drugs differently, their bodies may react to drugs differently, and diseases themselves may have different causes or underlying mechanisms in kids than adults.

Dr. Daniel Frattarelli, a pediatrician in Dearborn, Mich., and chair of the American Academy of Pediatrics Drug Committee, said the numbers represent a big improvement over recent history. But 90 percent of medications used to treat newborns still have not been adequately studied, he said.

"We still have a huge problem with newborns," he said.

"It's great that we've made all of this progress in older children, but for babies, they're very vulnerable, they're often in the neonatal ICU [intensive care unit], and their metabolism is different even than for older children," Frattarelli said.

In 1975, the last time a similar study of drug labels was conducted, only 22 percent of medications had information about use in children, Murphy said.

Experts at that time wrote "we have to stop treating children like second-class citizens and basically experimenting on them because we haven't studied these products adequately," said Murphy.

Pediatric information on many drugs is limited largely because drug makers don't often study drugs in children. Ethical issues are one deterrent, Murphy said. Financial concerns are another. Kids typically

make up a small sliver of the population that will be taking the drugs, so developing and testing drugs for use in children "isn't a good business model," she said.

Frattarelli credits two laws with boosting pediatric drug testing. The Best Pharmaceuticals for Children Act, enacted in 1997, provides financial incentives to drug makers that conduct clinical trials in children when new drugs come to market, and the 2003 Pediatric Research Equity Act requires pharmaceutical companies to assess the safety and effectiveness of certain drugs in kids.

Since the laws were enacted, more than 400 drug labels have been altered to reflect a better understanding of whether the drugs work in kids and the correct dose for them, Murphy said.

Still, obstacles remain, such as high drug development costs and a failure of many drugs to make it to market. For these reasons, Kate Connors, director of communications for Pharmaceutical Research & Manufacturers of America, an industry association, said drug makers may not want to take on the expense of conducting trials in children.

"We are highly supportive of these programs, which have helped to incentivize significant increases in pediatric research," Connors said. "There are many reasons why research in pediatric patients has not been widely available. For one, the cost of developing a new drug is already incredibly high, now exceeding $1 billion, and pediatric trials would add to this cost. So for a medicine that may not be anticipated for use in children, it may not be worthwhile to conduct pediatric studies."

The study authors, writing in the May 9 issue of the *Journal of the American Medical Association*, said additional legislation is needed to increase pediatric clinical trials and improve labeling. Current legislation comes up for reauthorization this year, and the American Academy of

Pediatrics is requesting that the laws regarding drug-testing in newborns be strengthened, Frattarelli said.

More information: The U.S. Food and Drug Administration has more on www.fda.gov/AboutFDA/Transpare … Basics/ucm228249.htm " target="_new">the study of drugs in children.