Study exposes need for pediatric cardiac devices

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Nearly two-thirds of children who undergo routine interventional cardiology procedures
-- those involving a catheter to treat structural disorders of the heart -- may be receiving treatment with a device that's being used for an off-label application.

This finding underscores the need for the appropriate agencies to include pediatric applications when reviewing and approving cardiac device processes in the United States, according to Robert Beekman, MD, a pediatric cardiologist at the Heart Institute, Cincinnati Children's Hospital Medical Center.

Dr. Beekman presents the study today at the annual meeting of the American College of Cardiology in Orlando, FL.

Off-label use of these devices - their use for purposes other than which they were approved -- is standard of care in pediatric cardiology, but disadvantages remain, according to Dr. Beekman. "There is a lack of regulatory oversight to assure device safety and efficacy, and industry is economically unable to refine devices for off-label pediatric applications. Children deserve to benefit from new and refined cardiac devices designed explicitly for their conditions."

Dr. Beekman and his colleagues at Cincinnati Children' reviewed medical records of 473 children who underwent 595 transcatheter procedures at Cincinnati Children's between 2005 and 2008.

Interventional cardiologists used an approved device for an off-label application in 63 percent of the patients and in half of all procedures performed.

The most frequent off-label procedures were stent implantations, which were 99 percent off label, and balloon dilations, which were 78 percent off label.

"The medical community, industry and the FDA must work together to make appropriate devices available for children and to ensure safety for the most vulnerable patients," says Dr. Beekman.

Source: Cincinnati Children's Hospital Medical Center