Pediatric devices still have few premarket studies in children

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(HealthDay)—Most high-risk pediatric devices are approved based on trials that don't involve children under 18 years of age, according to a study published online April 14 in *Pediatrics*.

Thomas J. Hwang, from Harvard University in Boston, and colleagues identified all high-risk (class III) devices approved through the U.S. Food and Drug Administration's premarket approval (PMA) or humanitarian device exemption pathways for use in children (between 2008 and 2011). Clinical trial design (randomization, blinding, controls, and types of end points), age distribution of trial participants, and FDA-mandated postmarketing trials were identified.

The researchers found that, over the study period, 22 devices were approved for use in children via the PMA pathway and three via the humanitarian device exemption pathway. The majority of devices (88 percent) qualified as pediatric despite minimum approval ages of ≥18

years (the FDA considers patients aged 18 to 21 years old as pediatric). Nonrandomized (59 percent), open-label (68 percent) studies with surrogate effectiveness end points (77 percent) contributed to most device approvals. Most devices (84 percent) were not studied in any patients younger than 18 years of age. Roughly three-quarters of devices were mandated to have postmarketing studies, although only three required enrollment of pediatric patients.

"Most high-risk pediatric devices are approved on the basis of trials in patients ≥18 years old, with few pediatric patients exposed to the devices before market availability," the authors write.

More information: Abstract
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