Making medications safer for newborns

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Although new drugs must be shown to be both safe and effective for approval by the Food and Drug Administration, sick newborns receive most of their drug treatment off-label and without the evidence provided for adults and older children.

A new editorial looks at the challenges of performing clinical trials in newborns, from the reluctance of parents to enroll their infants to the lack of experience of pediatricians and neonatologists in conducting clinical research.

Fortunately, new efforts to increase the study of drugs in newborns and to improve the efficiency of these studies are underway.

"We can look to a future when neonatal drug therapy has the same solid data base that is provided for treatment of older children and adults," wrote the authors of the *British Journal of Clinical Pharmacology* editorial.

More information: Newborns still lack drug data to guide therapy. DOI: 10.1111/bcp.13074

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