

Best Pharmaceuticals for Children Act (BPCA) Trimethoprim-Sulfamethoxazole

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Trimethoprim-Sulfamethoxazole (TMP-SMX), a combination antibacterial product, is currently approved by the U.S. Food and Drug Administration (FDA) to treat urinary tract infections, shigellosis, acute middle ear infections, and Pneumocystis jiroveci infections in children 2 months of age and older and is labeled for preventive care against susceptible bacteria. Pediatric dose recommendations in the current label are estimated from adult data. TMP-SMX is also prescribed off-label to treat community-acquired methicillin-resistant Staphylococcus aureus infections. However, TMP-SMX is not recommended for children younger than 2 months of age.

Studies

Pharmacokinetics (PK) of Understudied Drugs Administered to Children per Standard of Care (POP01) is a multicenter, prospective study on the PK and safety of understudied drugs, including TMP-SMX, in children younger than 21 years of age who receive certain drugs per standard of care.

Pharmacokinetics describe how a drug is absorbed, distributed, metabolized, and eliminated from the body. Population PK models are developed from blood samples of patients taking the drug and give an estimation of the variability of effects of the drug in a given patient population. These types of models can be used in the future to determine more precise dosing to patients.

A total of 153 participants receiving oral or enteral TMP-SMX contributed 240 plasma samples to the PK analysis. Of the total study population, 46 were younger than 2 years of age; 25 were between 2 years and 6 years of age; and 82 were older than 6 years of age.

Findings

- A population PK model for TMP-SMX was successfully developed in full term infants and children ([PMID: 26039810](https://pubmed.ncbi.nlm.nih.gov/326039810/)).
- **Key Outcome:** Higher doses of TMP-SMX may be necessary to treat infections in full-term infants and in children younger than age 21 years.

Resources

- NICHD's [Data and Specimen Hub](https://dash.nichd.nih.gov/study/19019) provides an overview of the study population and, for registered users, free access to datasets, study reports and documentation.
 - <https://dash.nichd.nih.gov/study/19019>
- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT01431326>
- FDA Labels: Tablet - <https://bit.ly/2GOZ28M>
Pediatric Oral Suspension - <https://bit.ly/3iHM8Xt>

About BPCA: The NICHD-led BPCA program at NIH helps advance pediatric drug research & development and improves information about and labeling for drugs used in children. The program identifies research gaps in pediatric therapeutics, prioritizes drugs in need of further study, supports research training, and sponsors clinical studies of prioritized drugs through the Pediatric Trials Network. Learn more at <https://www.nichd.nih.gov/BPCA>.

