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**169. Adverse Events in Pediatric Patients Treated with COVID-19 Therapeutics Reported to the FDA ACMT COVID-19 ToxIC (FACT) Pharmacovigilance Project**

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**Background:** The COVID-19 pandemic prompted a surge in the development and repurposing of approved and unapproved therapeutics for the SARS-CoV-2 virus. Due to differences in physiology and risks, pediatric patients were often excluded from trials examining the safety of COVID-19 therapeutics. Despite the paucity of safety data, pediatric patients are often treated with COVID-19 therapeutics and are vulnerable to adverse events (AEs).

**Methods:** This is a case series of AEs in pediatric patients associated with COVID-19 therapeutics submitted to the FDA ACMT COVID-19 ToxIC (FACT) Pharmacovigilance Project between November 23, 2020, and September 21, 2022. FACT is an ongoing toxicosurveillance project at 17 sites focusing on identifying AEs to COVID-19 therapeutics. Cases are identified via site-specific mechanisms, including direct contact, provider or pharmacist referral, or chart review. The inclusion criteria in this subset analysis were patients under 18 years of age with a suspected AE after a COVID-19 therapeutic.

**Results:** Of the 1,072 cases reported to FACT during the study period, 27 (2.5%) cases were in pediatric patients. Patients' ages ranged from 5 months to 18 years with a median of 13 years (IQR 4-17). Seventy percent of patients had known or presumed COVID. The majority of AEs were in patients treated for COVID-19 with remdesivir, monoclonal antibodies, and vitamins. The most common AE was bradycardia (6 cases), 5 of which were associated with remdesivir (83%). However, patients developed a wide range of AEs.

**Conclusion:** Pediatric patients represent a high-risk group for AE from COVID-19 therapeutics as they are often excluded from medical trials. This data displays AEs that occurred in pediatric patients exposed to COVID-19 therapeutics. Further study and analysis are needed to evaluate the effects of these therapies on pediatric patients. The FACT project is ongoing and will continue to identify AEs associated with COVID-19 therapeutics.