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EUAs address medical device needs of pediatric patients during pandemic

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During the COVID-19 pandemic, the Food and Drug Administration (FDA) has used emergency use authorizations (EUAs) to help make certain medical products available to patients when there are no adequate, approved and available alternatives. While clinicians may be aware of EUAs issued for drug and biological therapeutics, EUAs also have been issued for diagnostic and therapeutic devices.

As of December 2020, the FDA had issued approximately 300 EUAs for COVID-19 molecular, antigen and serology tests. EUAs for COVID-19 tests generally have not been limited to a specific age range.

The FDA also has issued "umbrella" EUAs for ventilators, surgical masks and respirators to help increase the availability of these devices. More than a dozen ventilators are authorized for use in pediatric patients from birth through 21 years.

With rising hospitalizations due to COVID-19, other routinely used medical devices may become scarce for hospitalized patients, including pediatric patients.

"We should not forget the needs of children with respect to critically needed medical devices during the COVID-19 pandemic," said Joy Samuels-Reid, M.D., pediatric medical officer at the FDA's Center for Devices and Radiological Health.

The FDA has received EUA requests for COVID-related medical devices, including infusion pump systems, continuous positive airway pressure machines, airway clearance devices and anesthesia gas machines. The FDA supports sponsors seeking to ensure these devices are programmed to meet the specific needs of pediatric patients. For example, the FDA issued an EUA for a device that provides continuous renal replacement therapy and can be used in patients weighing 8 to 20 kilograms with lower blood volume or patients who have acute renal failure, fluid overload or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment.

The FDA continues to stress the importance of not losing sight of pediatric patients' needs during the COVID-19 pandemic.

Resources

- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices
- In Vitro Diagnostics EUAs
- Emergency Use Authorization for Prismaflex HF20 Set
- Premarket Assessment of Pediatric Medical Devices: Guidance for Industry and FDA Staff
- Additional FDA Update columns