More Transparency Needed for COVID-19 Emergency Authorizations

To improve public trust, the US Food and Drug Administration (FDA) should be more transparent in publicly disclosing its reviews of safety and effectiveness data leading to Emergency Use Authorization (EUA) of coronavirus disease 2019 (COVID-19) vaccines and treatments, according to a recent report from the US Government Accountability Office (GAO).

In compiling its report, the GAO reviewed federal laws and documents and interviewed officials from the FDA, a public health association, and 9 organizations representing a broad range of frontline health care professionals who are responding to the COVID-19 pandemic.

The FDA issued a guidance in January 2017 regarding its general recommendations and procedures applicable to all EUAs. It noted that the type and amount of data needed to support an EUA may vary widely, considering that authorization could be granted for many different kinds of medical products. Instead of specifying the minimum number or types of studies required, the guidance stated that it would assess effectiveness data and risk-benefit profiles on a case-by-case basis.

As of mid-November, the FDA had issued 4 EUAs for COVID-19 therapeutics, including 1 for a new use of chloroquine and hydroxychloroquine that it eventually revoked. The other 3 were for remdesivir, convalescent plasma, and bamlanivimab, a monoclonal antibody.

The agency issued a guidance in October 2020 to inform companies working on COVID-19 vaccines about what information is needed to support an EUA. On November 20, Pfizer and BioNTech submitted the first EUA request for a COVID-19 vaccine.

Although the FDA explains its EUA decisions in publicly available authorization letters and other supporting documents, it has not uniformly released information from its scientific reviews of each therapeutic’s safety and effectiveness data, the GAO noted.

“We understand the FDA’s reported constraints,” the report noted. “However, in light of the gravity of the pandemic and the need for a high degree of public confidence in FDA’s decisions, the agency should identify ways to uniformly disclose the information” as it does for approved drugs and biologics.

Postpartum Depression Persists Longer Than Previously Thought

Postpartum depression might persist for up to 3 years after giving birth, according to a recent study conducted by researchers from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

The American Academy of Pediatrics recommends that pediatricians screen mothers for postpartum depression at well-child visits until their baby is 6 months old. However, the NICHD study found that depressive symptoms persisted for some women for up to 3 years after childbirth.

“Our study indicates that six months may not be long enough to gauge depressive symptoms,” primary author Diane Putnick, PhD, a staff scientist in the NICHD Epidemiology Branch, said in a statement. “These long-term data are key to improving our understanding of mom’s mental health, which we know is critical to her child’s well-being and development.”

Putnick and coauthors analyzed data from 4866 mothers who were part of Upstate KIDS, a population-based birth cohort of babies born from 2008 to 2010 in New York state. The women provided depressive symptom assessments at 4, 12, 24, and 36 months postpartum.

Approximately a quarter of the women had elevated depressive symptoms at some point in the 3 years after their children were born. Some women had increasing depressive symptoms over the 3 years, while depressive symptoms in others declined over time. The authors said theirs is the first study to link gestational diabetes to persistent depressive symptoms for up to 3 years postpartum.

Clinicians should be aware that postpartum depression symptoms follow different trajectories and can persist for at least 3 years, the authors noted. For that reason, they said, mothers should be assessed early and late in the postpartum period, which should be extended to at least 2 years.

Pharmacies Partner With HHS to Provide COVID-19 Vaccines

Chain and independent pharmacies have partnered with the federal government to maximize access to coronavirus disease 2019 vaccines at no cost when they’re available, the US Department of Health and Human Services (HHS) recently announced.

The program covers about 60% of pharmacies in the 50 states, the District of Columbia, Puerto Rico, and the US Virgin Islands, according to HHS.

The vast majority of people in the US live within 5 miles of a pharmacy, HHS Secretary Alex Azar noted in a statement. Participating chains include drugstores such as CVS and Rite Aid and supermarkets with pharmacies, such as Albertsons, Kroger, and Publix.

“Since 2012, CDC [US Centers for Disease Control and Prevention] has worked extensively with pharmacies to improve pandemic preparedness, conduct vaccine throughput exercises, and assess store and organizational response capabilities,” CDC Director Robert Redfield, MD, said in a statement. – Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.