HealthCap
RISK MANAGEMENT SERVICES

COVID-19 Vaccine Safety Surveillance

The Center for Biologics Evaluation and Research (CBER) at the FDA is monitoring the safety of authorized COVID-19 vaccines through both passive and active safety surveillance systems. CBER is doing so in collaboration with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other academic and large non-government healthcare data systems. In addition, CBER participates actively in ongoing international pharmacovigilance efforts, including those organized by the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO). These efforts are in addition to the pharmacovigilance efforts being undertaken by the individual manufacturers for authorized vaccines. A coordinated and overlapping approach using state-of the art technologies has been implemented.

Passive Surveillance

Passive surveillance is defined as unsolicited reports of adverse events that are sent to a central database or health authority. In the United States, these are received and entered into the Vaccine Adverse Event Reporting System (VAERS) that is co-managed by FDA and CDC. In the current pandemic, these reports are being used to monitor the occurrence of both known adverse events, as providers of COVID-19 vaccines are required to report serious adverse events to VAERS. FDA efforts complement those of the v-safe text-based monitoring system for adverse events that CDC has implemented. An example of the work done with passive safety surveillance during the current pandemic has been the evaluation of severe allergic reactions following vaccination with the authorized mRNA-based COVID-19 vaccines. Through this work, we have come to understand that these reactions are quite rare, happening in less than 1 in 200,000 vaccinated individuals.

Active Surveillance

Active surveillance involves proactively obtaining and rapidly analyzing information occurring in millions of individuals recorded in large healthcare data systems to verify safety signals identified through passive surveillance or to detect additional safety signals that may not have been reported as adverse events to passive surveillance systems. FDA is conducting active surveillance using the Sentinel BEST (Biologics Effectiveness and Safety) System and the CMS system, and is also collaborating with other federal and non-federal partners.

BEST

To elaborate further, the BEST system, which is part of the Sentinel initiative, comprises large-scale claims data, electronic health records (EHR), and linked claims-EHR databases with a data lag of approximately three months. The system makes use of multiple data sources and enables rapid queries to detect or evaluate adverse events as well as studies to answer specific safety questions for vaccines. The linked claims-EHR database makes it possible to study the safety of vaccines in sub-populations with pre-existing conditions or in pregnant women. The major partners for BEST currently are Acumen, IBM Federal HealthCare, IQVIA, and Columbia University and many affiliated partners such as MedStar Health, BlueCross BlueShield of America, the Observational Health Data Sciences and Informatics (OHDSI), OneFlorida, University of California and several others.

Using BEST, CBER plans to monitor about 15 adverse events External Link that have been seen with the deployment of previous vaccines but have yet to be associated with a safety concern for an authorized COVID-19 vaccine at this time. CBER further plans to use the BEST system to conduct more in-depth analyses should a safety concern be identified from sources such as VAERS.

CMS

CBER has worked over the past several years with CMS to develop capabilities for routine and time-sensitive assessments of the safety of vaccines for people 65 years of age and older using the Medicare Claims database. Because it was already in place, this system was immediately put into use for COVID-19 vaccine surveillance to monitor for adverse events.

During the current pandemic, FDA, CMS, and CDC have already used the Medicare data to publish a study showing that frailty, comorbidities, and race/ethnicity were strong risk factors of COVID-19 hospitalization and death among the U.S. elderly.

In summary, in collaboration and coordination with several different partners, CBER has assembled passive and active surveillance systems that can detect and refine safety findings with the recently authorized COVID-19 vaccines in a relatively rapid manner. These systems can also potentially be leveraged to assess safety in specific subpopulations and to assess vaccine effectiveness, including against emerging variants.

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