International Alliance for Biological Standardization

The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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Real-world vaccine safety evidence and public health decision making in the United States during the COVID-19 vaccination program

Dr. Tom Shimabukuro**,** Director, Immunization Safety Office U.S. Centers for Disease Control and Prevention (CDC)

The U.S. Centers for Disease Control and Prevention (CDC) uses multiple, complementary public health surveillance systems and programs to monitor the safety of vaccines authorized or licensed for use in the United States. COVID-19 vaccines were administered under the most intensive vaccine safety monitoring effort in U.S. history. During the pandemic vaccination program, >676 million COVID-19 vaccine doses were administered in United States and 81.4% of the population received at least one dose of a COVID-19 vaccine. Two examples highlight the effectiveness of CDC's vaccine safety monitoring programs in generating actionable real-world evidence, myocarditis following the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines and thrombosis with thrombocytopenia syndrome (TTS) following the Janssen adenoviral-vectored COVID-19 vaccine. In these two examples, CDC vaccine safety monitoring systems detected and assessed safety signals and quantified the risk of these adverse events following vaccination. This real-world evidence contributed to regulatory and public health action. Warnings were added to regulatory documents, clinical considerations were updated, and vaccine recommendations were issued, including an eventual preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen adenoviral-vectored COVID-19 vaccine. These actions informed healthcare providers and policy makers and protected and informed the public.