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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Example of use of RWE that supported decision-making (VE against symptomatic infection, duration, mix and match, booster)

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Background: AZD1222 (ChAdOx1 nCoV-19; Vaxzevria; AstraZeneca) is a COVID-19 adenoviral vector vaccine, first approved for use in the United Kingdom on 30 Dec 2020 and European Union on 29 Jan 2021. More affordable and stable at ambient temperatures than mRNA vaccines, during the pandemic, >3 billion doses were distributed to >180 countries, with two-thirds going to low/middle-income countries, resulting in >6 million lives saved during the first 12 months of use. Similar to mRNA vaccines, expert review of 79 real-world evidence (RWE) studies showed 93% protection against COVID-19 hospitalization for the primary series, with effectiveness waning over time. Further effectiveness studies suggest that booster dose protection against severe disease was equivalent to monovalent mRNA vaccines.

Challenges: Due to the rapidly changing variant landscape, there has been increasing reliance on real world evidence to demonstrate COVID-19 vaccine effectiveness and inform decision making. However, according to the International Vaccine Access Center, of the 495 COVID-19 vaccine effectiveness studies in preprint/published literature as of 05 Sep 2023, 73% were conducted in Europe or North America, having impact on global decision making for vaccines used primarily in low/middle income countries. This is due in part to the stronger health research infrastructure of North American/European countries, facilitating large scale studies of vaccine effectiveness using secondary data sources for example, but also earlier vaccine access/faster initiation of vaccination/booster programs in those countries.

Proposed Approach: Efforts are needed to build up post-marketing research infrastructure and capabilities in low/middle income countries to more rapidly assess vaccine effectiveness and support study designs that do not fully rely on primary data collection. Creation of real-world evidence hubs in key, early adopter countries could be warranted.

Conclusions: With the increasing importance of RWE to inform decision making, it is important to consider the balance between effectiveness data from high versus low/middle income countries and ensure that the most appropriate, timely data are available to inform global-level decisions.