Emerging evidence on additional doses of COVID-19 vaccines and their safety: Meeting objectives

Phil Krause, M.D.
Chair, WHO COVID Vaccines Research Expert Group
October 25, 2021
Safety

Myocarditis/pericarditis have emerged as rare adverse events after vaccination with mRNA vaccines, especially after 2nd dose and in younger males

Some reports, including from North America and Nordic countries, have suggested that myocarditis risk may be greater with Moderna vaccine than Pfizer

Some (e.g., Sweden, Norway, Finland, Ontario) have taken action based on these data

To date, much of this information has not been publicly presented

Not all data are consistent with a higher risk of myocarditis after Moderna vaccine

Myocarditis risk has been raised as a special concern for boosting, pediatrics

WHO supports transparency and open discussion

One goal for this meeting is to facilitate expert discussion on these data, in the hopes of developing an international research agenda that could address the issues
Safety (continued)

We will also discuss other safety follow-up in the hope of facilitating international research collaboration in support of an international research agenda for COVID vaccine safety.

We have a full slate of presenters including studies on myocarditis, vaccine developers, regulators, and other experts, who will present their perspectives on what we currently know and need to know about real-world COVID vaccine safety.
Additional doses of vaccine: necessity and expected outcomes of boosting

WHO has raised ethical objections to boosting strategies that further concentrate available doses of vaccine in wealthier countries, reducing the chances that people at high risk in developing countries can access vaccines.

WHO Consultation 8/13/2021: Can booster doses contribute to control this pandemic: what research is needed?

Lancet paper (9/13/2021) summarized the literature indicating no need for widespread boosting in the general population, and called for transparent science-based decision-making.

Additional data are now available.

Some countries have taken regulatory action and made recommendations about boosters.

Do new data change thinking about which individuals are likely to derive meaningful benefit from additional vaccine doses?

What are the remaining research gaps?