

Announcements

Establishment of the NIAC Technical Working Group on COVID-19 Vaccines

COVID-19 Vaccines Technical Working Group

Vaccines against the COVID-19 virus are being developed in China and other countries at an accelerated pace to prevent and control COVID-19. Strategies and policy for the use of the vaccines are based on scientific evidence including epidemiology, vaccinology, health economics, ethics, and production factors. The National Immunization Advisory Committee (NIAC) makes evidence-based recommendations for the use of vaccines and is supported by working groups of technical experts. We report the establishment of a technical working group for COVID-19 vaccines, its terms of references, anticipated products, and membership.

The NIAC was established in 2017 by China's National Health Commission (NHC) at the request of the State Council to make evidence-based recommendations to the NHC on the inclusion of vaccines in the Expanded Program on Immunization (EPI) and recommendations for use of vaccines (1). NIAC was included in the vaccine law enacted by the People's Congress in 2019. Chinese Center for Disease Control and Prevention (China CDC) scientists, with NIAC members and external experts, lead and staff technical working groups (TWGs) to support the NIAC vaccine recommendations using an evidence-to-recommendation framework to formulate draft vaccine recommendations for consideration by the NIAC (2). We report the establishment of a NIAC TWG for COVID-19 vaccines, describe its terms of reference and anticipated products, and provide contact information for the TWG.

PURPOSE

The purpose of the technical working group on COVID-19 vaccines is to support the NIAC in making and keeping up-to-date evidence-based recommendations to the NHC on use of COVID-19 vaccines in China based on 1) evidence about the epidemiology of COVID-19, 2) awareness of COVID-19 vaccines and their characteristics, development,

evaluations, and projections of production, 3) awareness of clinical trials and regulatory pathways, 4) evidence from public engagement with likely vaccine target populations on acceptability of vaccines and potential recommendations, and 5) evidence that will emerge from safety, effectiveness, and implementation monitoring.

COVID-19 vaccines will almost certainly be necessary for the COVID-19 pandemic response, including for protection of health care workers and responders, maintenance of essential services, and for immunizing the population to stop risk of COVID-19 infection and transmission.

There are currently no approved vaccines against the COVID-19 virus infection, but COVID-19 vaccines are being developed rapidly in China and other countries and vaccine candidates are entering Phase I human clinical trials. Several strategies are being used for vaccine development including subunit vaccines, inactivated virus vaccines, adenovirus vectored vaccine, live attenuated influenza virus vectored vaccine, and nucleic acid vaccine (mRNA, DNA) (3). The characteristics and safety profiles of vaccines that will become available are largely unknown, and since no coronavirus vaccines have ever been licensed in any country, including human-tested SARS and MERS vaccines, there is no direct experience regarding coronavirus vaccine immunization programs to draw from.

Pragmatic planning for science-based recommendations on the use of COVID-19 vaccines can contribute to the public health response to the COVID-19 epidemic. Planning and communications encompass the entire lifecycle of COVID-19 vaccines from development and testing through its use, monitoring, and injury-related compensation. Vaccine clinical trials can be planned and conducted with the uses of the vaccines in mind, including inclusion of study populations that resemble likely vaccine target populations and therefore minimizing the need for off-label use of licensed vaccines. Without adequate planning and communication to the public and

stakeholders, there is potential for suboptimal and inequitable use of vaccines and for social disruptions due to a mismatch between actual and expected vaccine implementation from the public, government, and other key stakeholders. Because the NIAC has a responsibility to make recommendations for inclusion of vaccines into the EPI system, the committee has an important role in supporting the availability, affordability, and strategic use of COVID-19 vaccines in China.

TERMS OF REFERENCE

Monitor COVID-19 vaccines development. Be aware of and monitor COVID-19 vaccine research and development, technical strategies for clinical evaluation, and market authorization policies; provide suggestions for clinical trials, vaccine evaluations, and preparation for production capacity during public health emergencies.

Support NIAC immunization policy development. Provide technical support to the NIAC with considerations for prioritization and sequencing of potential target populations, immunization schedules, and other COVID-19 vaccine policy recommendations.

Prepare for and monitor COVID-19 vaccines use. Develop and recommend strategies for post-marketing safety surveillance and assessment of effectiveness and implementation of COVID-19 vaccines.

Develop vaccination education and communication materials. Prepare materials for professional education and public communications for COVID-19 vaccines and immunization strategies and policies.

TWG COMPOSITION AND PRODUCTS

The TWG and its consultants include NIAC members, China CDC staff, academics, industry leaders, and members of civil society organizations that collectively have expertise in COVID-19 epidemiology, medicine, public health, laboratory, infectious disease, vaccine regulation, manufacturing, vaccine safety and pharmacovigilance, clinical trials,

ethics, law, and communications.

The primary product of the technical working group will be technical guidelines on the use of COVID-19 vaccines in China. The TWG will publish periodic reports in *China CDC Weekly* (CCDCW) and the *Chinese Journal of Vaccines and Immunization* (CJVI) on the TWG products and activities, the status of vaccines being considered for use in China, results of policy-relevant research and evaluations, meeting reports, availability of material for training and education, and communications messages.

TWG point of contact is Dr. Fuzhen Wang, TWG Secretary (wangfz@chinacdc.cn).

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