

## The National Immunization Advisory Committee in China: Roles of National Experts in Making Evidence-Based Recommendations for Immunization

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In 2017, the State Council requested the National Health and Family Planning Commission (NHFPC), known as the Ministry of Health (MoH) before 2013 and as the National Health Commission (NHC) after 2018, to establish China's National Immunization Advisory Committee (NIAC)(1). The NIAC acts as China's National Immunization Technical Advisory Group (NITAG) — a deliberative body of national experts who advise national authorities and policy makers with evidence-based recommendations on immunization policy and program (2–3).

NIAC was preceded by the Experts Advisory Committee on the Immunization Program (EACIP), which was established by the MoH in 1982 and reaffirmed in 1988, 1992, 1997, and 2004 with membership expanding from 26 to 33 members all appointed by the MoH (4). In September 2010, the EACIP was again affirmed with 29 experts and was made a sub-group of the Experts Committee on Disease Control and Prevention under the MoH.

In the past 35 years, the EACIP played an important role in advancing the national immunization schedule, including drafting and reviewing technical documents, relevant laws, and regulations. The EACIP, however, was not tasked with recommending new vaccines to be introduced into the national Expanded Program on Immunization (EPI). Indeed, China has not introduced any new EPI vaccines since 2008 (4), with the sole exception of replacing the first oral poliomyelitis vaccine (OPV) dose with inactivated poliomyelitis vaccine (IPV) in 2016 as part of the globally synchronized poliovirus vaccine switch.

### Establishing the NIAC

In 2010, the 65th World Health Assembly endorsed the Global Vaccine Action Plan 2011-2020 (GVAP) with the goal of all Member States developing a NITAG (5). The World Health Organization and the Global NITAG Network (GNN) provide technical

support for developing NITAGs and achieving this GVAP goal (2).

In 2016, the NHFPC EPI division initiated deliberations on a process to incorporate new vaccines into EPI. The Chinese Center for Disease Control and Prevention (China CDC) and NHFPC EPI division conducted a full lifecycle analysis on adding new vaccines to EPI, held an international workshop on country-specific practices of introducing a new vaccine, and conducted a study tour to Canada and the United States to meet with their NITAGs (6).

In January 2017, China's State Council released a guideline to strengthen vaccine management and circulation with the intent of improving vaccine quality and immunization safety (1). This guideline requested formation of a committee of national experts on vaccines and immunization to make recommendations for gradually introducing additional qualified and affordable vaccines into the government's EPI system and for updating recommendations of current EPI vaccines. In October 2017, the NHFPC issued an official document, "Notice on Establishing the National Immunization Advisory Committee", which reshaped the EACIP. The committee's name was formally changed to NIAC, and a charter and terms of reference were released (7).

### NIAC Terms of Reference

According to State Council guidance, NIAC was tasked with making recommendations for introducing qualified, efficient, and affordable vaccines into the EPI system and to ensure access to improved immunization services. NIAC's terms of reference (TOR) indicated that "the main responsibilities of NIAC were to 1) assess evidence of vaccine-preventable burdens of disease and the safety, effectiveness, health economics, and production and supply capacity of new vaccines for recommending introduction into EPI; 2) update recommendations for current EPI vaccines;

and 3) provide evidence-based recommendations on immunization program strategies and management” (7).

## NIAC Membership

NIAC has 27 voting members from across China who are recognized experts in relevant fields including epidemiology, biostatistics, microbiology, vaccinology, clinical medicine (pediatrics, internal medicine, immunology, and infectious diseases), health policy, economics, and immunization practices. Members are appointed for three-year terms that may be renewed once. NIAC has one chair and two vice chairs who are also appointed for three-year terms. The selection procedure for NIAC members is as follows: 1) the Secretariat nominates 50% more candidates than are needed to fill the NIAC roster; 2) potential NIAC members indicate agreement with their candidacies and obtain approval from their institutions; 3) the Secretariat provides formal nominations to NHC, and 4) the NHC Minister selects and issues a formal document indicating membership (7). The current NIAC members are from 19 different organizations covering seven fields of expertise.

## NIAC Operations

The NIAC Secretariat is located in MoH’s Department of Disease Control’s EPI Division and is supported technically by the China CDC’s National Immunization Program. The Secretariat oversees preparatory work for NIAC meetings, including logistical support and compiling requested documents, and for conveying NIAC recommendations to the MoH for a final decision. The NIAC has at least one full-day, in-person meeting each year, and additional meetings may be held when urgent health situations need recommendations. Currently, meetings are closed to the public, and meeting minutes are made available on a confidential basis to members and invited participants.

The scope of the NIAC encompasses all questions concerning vaccines and immunization. The NIAC meeting agenda is informed by changes in the

epidemiology of vaccine-preventable diseases, new vaccination products, and new evidence about existing products. The NIAC makes recommendations on whether or not to use a vaccine, about revisions to the national immunization schedule, and about vaccination of high-risk groups, regardless of age, for all vaccine-preventable diseases. Technical Working Groups (TWG)\* are responsible for gathering, analyzing, and summarizing all available and relevant evidence and for formulating recommendations for NIAC consideration, discussion, and voting.

External experts can be invited to NIAC meetings by the Secretariat to provide data and evidence. In future meetings, liaison members and *ex officio* representatives are expected to bring their knowledge and input to NIAC discussions and express the views of their organizations. Vaccine industry representatives cannot be members of the NIAC or the TWGs and cannot participate in closed-group discussions. Industry experts can provide information about vaccines to the TWGs as requested and may be invited to make presentations at TWG meetings. The vaccine industry cannot provide funding to the NIAC or the TWGs.

At each meeting, NIAC members declare potential conflicts of interest and a register of such interests is maintained by the Secretariat. Potential conflicts are classified into specific and non-specific interests. Those with personal, specific interests are asked to leave the meeting during discussions and decision making, and those with non-specific interest can participate in discussions but not in decision making.

Prior to NIAC meetings, members will have received comprehensive background materials from the TWGs. At the meeting, a TWG lead will present draft recommendations and relevant evidence for discussion. “Yes” votes from at least 80% of members present at a meeting are needed to pass a recommendation, and then the recommendation document is sent to the NIAC chair for review and approval. The Secretariat will transform NIAC recommendations into official documents for MoH leadership decision making. The NHC will work with the Ministry of Finance to obtain the necessary resources, and the entire recommendation package is sent to the State Council for final approval and implementation.

\* To augment the effectiveness of NIAC, groups of experts – Technical Working Groups (TWG), were established by China CDC with the authorization of MoH. The Director of China CDC, who is responsible for EPI, acts as the TWG Chair. There are currently 18 active Working Groups (WGs). These include three permanent WGs (an Immunization Schedule WG, an Immunization Practices WG, and an Evidence-based Decision Making Methods WG) and 15 task-oriented WGs for specific vaccines (polio, measles-mumps-rubella, DTaP, meningococcal, rabies, cholera, influenza, hepatitis B, hepatitis E, pneumococcal, *Haemophilus influenzae* type b, varicella, rotavirus, human papillomavirus, and hemorrhagic fever). Each WG operates under specific TORs as determined by the TWG chair and WG lead when the WG is established.

## Key Recommendations from the NIAC in 2018 and 2019

In April 2018 and May 2019, the first and second NIAC meetings discussed and passed four voting items: 1) changing the polio vaccine schedule from 1 dose of IPV followed by 3 doses of bivalent oral polio vaccine (bOPV) to 2 doses of IPV followed by 2 doses of bOPV; 2) replacing the first dose of measles-containing vaccine (MR) with MMR to change to a 2-dose MMR schedule; 3) updating the 2019 national EPI schedule, and 4) providing the first-ever national guidance for post-injury use of tetanus vaccine and antitoxin. These recommendations have been transferred to NHC leadership for decision making. In addition to the four voting items, NIAC discussed and rendered opinions on Hib, DTaP, influenza, and rabies vaccination strategies, and an action plan for measles and rubella elimination.

### Discussion

Having been designed from the perspective of global NITAG experiences to solve longstanding challenges with China's immunization policy development, China's NIAC is qualitatively different from its predecessors. The State Council and subsequently the People's Congress, the highest legislative body of China, requested establishment of the NIAC, which gave an immunization advisory committee visibility and legal standing in public law for the first time in China (8). The TWG support structure is formally defined in NIAC's charter, allowing NIAC access to specific policy expertise while empowering subject matter experts led by China CDC scientists to synthesize available evidence and make the initial drafts of policy recommendations that the NIAC will consider.

Although the structures and legal standing of NIAC are established, the operation of NIAC in the development of lasting evidence-informed recommendations has yet to be shown. The ability of NIAC recommendations to be accepted by government and implemented across China is still developing, but the NIAC has had a positive beginning with strong recommendations on polio and MMR vaccines, wound management for tetanus, and eliminating unnecessary contraindications in the routine vaccination schedule.

The NIAC will face many challenges. For example, one challenge is "off-label" vaccine recommendations that deviate from manufacturers' package inserts to cover new vaccine indications or vaccination strategies based on evidence emerging after vaccine licensure. Another challenge is obtaining timely and reliable funding to implement NIAC recommendations. A third is determining whether NIAC recommendations for non-EPI vaccines will be considered medical standards of care as is the case for EPI vaccine recommendations. In addition, the NIAC might be limited by the TWGs capacity and means to monitor the safety, effectiveness, and impact of policy recommendations, which provide the NIAC essential data and scientific evidence for vaccine policy recommendations and their periodic optimization. Publication of technical guidelines and NIAC recommendations in the *China CDC Weekly* will share with the public and other stakeholders the processes and evidence on which vaccine recommendations are made.

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