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Foreword

Message from Deputy Editor-in-Chief Zijian Feng — Vaccine Policy as Evidence-Based Public Health Decision Making in Action

Public health is applying science to help people live safer, more productive, and healthier lives. Making evidence-based policy recommendations on the use of vaccines to prevent, control, and even eliminate vaccine-preventable infectious diseases serves as an example of public health in action.

Vaccines are one of the most important public health interventions ever developed as they have prevented suffering and death from infectious diseases with significant savings for the healthcare system, government, and society. But how vaccines are used has a strong impact on their efficacy, safety, and disease-prevention efficiency. Policy decisions on which vaccines to use, for whom they should be administered and not administered, and upon what schedule they should be given represent a public health "prescription" for all children, adolescents, and adults.

Effective vaccine policy-making requires a variety of expertises—medicine, vaccinology, public health, epidemiology, and economics—as well as an understanding how people for whom vaccines are recommended value various health outcomes. The focal point for evidence-based policy-making is a national immunization technical advisory group (NITAG) (*1*). The World Health Organization (WHO) recognizes the importance of evidence-based vaccine policy, and the WHO's Global Vaccine Action Plan, endorsed by the World Health Assembly, has a goal that all countries should have a NITAG to make vaccine policy by 2020. Global progress in developing NITAGs has largely been successful in the Global Vaccine Action Plan, as most countries have developed or are well on their way to develop their NITAGs (*2*).

China has a long history of vaccine advisory committees going back to 1982. In 2017, the State Council requested formation of a NITAG that uses five lines of evidence to make vaccine recommendations: burden of the disease the vaccine addresses, the vaccine's effectiveness, its safety, its cost-effectiveness, and its production capacity. In response to this request, the National Immunization Advisory Committee (NIAC) was conceived, developed, and approved in 2017. Importantly, the new vaccine law enacted this summer by the People's Congress recognized the NIAC as the evidence-based vaccine policy lead for China, which made the NIAC a legal entity and fulfilled a key WHO criterion for an effective NITAG (*3*). Vaccines and vaccine-preventable diseases are complex, and to extend the knowledge base for NIAC, Technical Working Groups of scientists specializing in the relevant diseases and vaccines synthesize all available evidence and craft evidence-informed policy options for NIAC to consider, vote on, and provide recommendations to the National Health Commission (NHC) for decision making and implementation.

With 27 voting members, the NIAC has the breadth of expertise required of a NITAG. The NIAC includes experts from academic institutions, clinical medicine, and public health. Its chair is Professor Chen Wang, a distinguished academician of the Chinese Academy of Engineering, leader of both Peking Union Medical College and Chinese Academy of Medical Sciences, and an expert in respiratory diseases. In partnership with academic experts, China CDC leads the Technical Working Groups that provide the NIAC with its depth of knowledge in specific diseases and vaccines. Currently, there are 15 task-oriented Technical Working Groups supporting NIAC on specific vaccines and vaccine-preventable diseases. China CDC also leads three permanent working groups—a general best-practices working group, a vaccine-safety working group, and an evidence-based recommendations methods working group. Together, the NIAC and its supporting working groups are developing evidence-based recommendations that ensure that China's use of vaccines is as safe and effective as possible.

A key role of the working groups is to ensure that vaccine policy is monitored carefully for emerging safety signals, changes in vaccine effectiveness, continued acceptability of recommendations, and changes in the impact of policy on disease. Evidence emerging from China CDC's monitoring is presented to the NIAC for updating vaccine policy to ensure that the immunization program uses vaccines in the most effective, safe, equitable, and efficient manner.

The NIAC has already changed vaccine policy for tens of millions of children in China. Ensuring the safest

protection from polio, the NIAC recommended substituting a dose of live, attenuated poliovirus vaccine with a second dose of inactivated poliovirus vaccine into the routine schedule. The NIAC added a second dose of protection from mumps, changing the schedule to two doses of measles-mumps-rubella (MMR) vaccine from the previous one dose of measles-rubella vaccine followed by the MMR vaccine. The NIAC also recommended changes to emergency wound management to reduce the use of potentially allergenic immunoglobulins and increase the use of the much-less-allergenic tetanus vaccine. Finally, the NIAC updated the routine immunization schedule to reduce the number of false contraindications to vaccination so that certain vulnerable children can also receive the benefits of vaccines.

China CDC Weekly is "the voice of China CDC", and will publish technical reports by the working groups and NHC-approved NIAC recommendations so that programs, clinicians and the public will be able to see and understand the scientific rationale for vaccine recommendations and policy. I believe that parents and the public will be pleased and reassured to see the care and thoughtfulness with which vaccine recommendations are made in China.

The future is bright for the NIAC and science-based vaccine policy. *China CDC Weekly* will document every step along the path to ensure that vaccination remains the safest, most effective way to protect children, adolescents, and adults from vaccine- preventable diseases in China.

Zijian Feng, MD
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Foreword

China CDC Weekly — A Step Forward for China's Public Health System and for Global Health Security

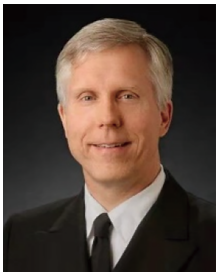
Congratulations to China CDC on the launch of the *China CDC Weekly*. Through timely, accurate reporting on public health surveillance, epidemiologic investigations, and emergency responses, and by sharing lessons learned and evidence-based recommendations for public health practice, this new publication will contribute to improving public health.

China is an active and strategic partner in global health security. As the home of one fifth of the world's population, the health of China is a key contributor to the health of the world. In addition, China's large population of livestock (*1*) creates risk of transmission of infectious diseases such as avian influenza; successful control of this and other zoonotic diseases is vitally important to China and the rest of the world. Finally, the rapid growth of China's international travel and trade—by land to its 14 neighboring countries and by air and sea to the rest of the world—makes timely detection, reporting, and control of communicable diseases critical for preventing the spread of such disease both into and out of China. Thus, China's progress in improving its own public health capacity along with its contributions to public health preparedness in other countries will play a significant, growing role in helping to ensure a world safe from infectious and other health threats.

The US and China have maintained a close partnership in public health for over four decades, and the *China CDC Weekly* marks an exciting new development in this relationship. The *China CDC Weekly* is modeled after the Morbidity and Mortality Weekly Report, or *MMWR*, which has been published by CDC since 1961 (*2*) and has consistently published important public health findings and recommendations relevant to the US and globally. Included among these have been many firsts, such as the first cases of what was later determined to be AIDS in 1981; the first cases of hantavirus pulmonary syndrome in 1993; the first cases of pandemic H1N1 influenza in 2009 and many more. Known for its clear, succinct writing style and with a reputation for accuracy, credibility, timeliness, relevance, and usefulness, *MMWR*, or "the voice of CDC" as it has been called, has evolved to be one of the leading sources of public health information and recommendations in the world (*2*).

We expect the new *China CDC Weekly* to join the ranks of important public health publications that promote a culture of rapid data sharing and transparency needed to quickly address public health problems. Moreover, we hope the *MMWR* and *China CDC Weekly* will develop a tradition of joint publication of articles relevant to the US, China, and the world, expanding rapid access to public health data and information to new audiences. The article, "Progress Toward Measles Elimination in the People's Republic of China, January 2013–June 2019", being jointly published this week in both publications can start such a tradition by focusing on a resurgent public health problem—measles—and sharing China's progress towards its elimination (*3*).

Health challenges are notoriously complex and at times can seem insurmountable. They can often be solved, however, through diligent surveillance and epidemiologic investigation, application of innovative and evidence-based interventions, timely and transparent data sharing, and maintenance of strong and effective partnerships. We look forward to the public health benefits that will follow from scientific findings soon to be shared rapidly and widely in the *China CDC Weekly*. This is cause for congratulations, appreciation, and celebration.



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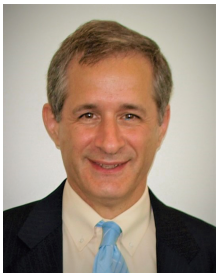

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Disclaimer: The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Preplanned Studies

Progress Toward Measles Elimination — China, January 2013-June 2019

Chao Ma[1]; Lance Rodewald[1]; Lixin Hao[1,#]; Qiru Su[1]; Yan Zhang[2]; Ning Wen[1]; Chunxiang Fan[1]; Hong Yang[1]; Huiming Luo[1]; Huaqing Wang[1]; James L. Goodson[3]; Zundong Yin[1]; Zijian Feng[1]

Editorial *China CDC Weekly* is a national public health bulletin published by the Chinese Center for Disease Control and Prevention. *China CDC Weekly* and *MMWR* have had a close collaborative relationship since 2014 when a team from China CDC first visited *MMWR* offices in preparation for the establishment of a public health bulletin. To commemorate this relationship, *China CDC Weekly* and *MMWR* will occasionally joint publish significant articles with broad relevance to the US, China, and the world to allow for rapid access to public health data.

Therefore, *China CDC Weekly* and *MMWR* have agreed to joint publish the article "Progress Toward Measles Elimination — China, January 2013-June 2019" in this week's publications (*China CDC Weekly* Vol. 1, No.2, Dec 6, 2019 and *MMWR* Vol. 68, No.48, Dec 6, 2019). Measles is a highly contagious viral disease that can spread quickly, and it remains a significant cause of death among young children worldwide despite the availability of a safe and effective vaccine. Measles is so important that all six World Health Organization regions have goals to eliminate the disease.

Data sharing and cooperation among countries and international organizations are critically important for eliminating and eventually eradicating measles worldwide. This joint publication uses measles surveillance data from China CDC and US CDC to illustrate the remarkable progress that China's immunization program has made toward eliminating measles, including reductions in the international spread of measles. The joint publication highlights nearly three decades of global collaboration in the struggle against this highly-infectious disease.

Summary

What is already known about this topic?

China has historically had high measles incidence and many associated deaths. A comprehensive measles elimination plan during 2006–2012 substantially reduced measles incidence; however, a resurgence occurred during 2013–2015.

What is added by this report?

In China, measles surveillance, outbreak response, research, and program evaluation were used to strengthen routine immunization and target immunization activities for eliminating measles. Measles incidence declined from 31 per million in 2015 to 2.8 in 2018; only one measles-associated death has been reported during 2018–June 2019.

What are the implications for public health practice?

The World Health Organization–recommended strategy to eliminate measles can be effective, including in large, densely populated countries like China.

In 2005, the World Health Organization (WHO) Western Pacific Region countries, including China, resolved to eliminate measles by 2012 or as soon as feasible thereafter (*1*). As of 2018, nine[*] of the 37 Western Pacific Region countries or areas[†] had eliminated[§] measles. China's Measles Elimination Action Plan 2006–2012 included strengthening routine immunization; conducting measles risk assessments, followed by supplementary immunization activities (SIAs) with measles-containing vaccine (MCV) at national and subnational levels; strengthening surveillance and laboratory capacity; and

[*] Australia, Brunei Darussalam, Cambodia, Hong Kong (China), Macao (China), Japan, New Zealand, South Korea, and Singapore.

[†] The Western Pacific Region, one of the six regions of WHO, consists of 37 countries and areas with a population of almost 1.9 billion, including American Samoa (USA), Australia, Brunei, Cambodia, China, Cook Islands, Federated States of Micronesia, Fiji, French Polynesia (France), Guam (USA), Hong Kong (China), Japan, Kiribati, Laos, Macao (China), Malaysia, Marshall Islands, Mongolia, Nauru, New Caledonia (France), New Zealand, Niue, Northern Mariana Islands (USA), Palau, Papua New Guinea, Philippines, Pitcairn Islands (UK), Samoa, Singapore, Solomon Islands, South Korea, Tokelau (New Zealand), Tonga, Tuvalu, Vanuatu, Vietnam, and Wallis and Futuna (France).

[§] Measles elimination is defined as the absence of endemic measles virus transmission in a defined geographical area (e.g., region or country) for ⩾12 months in the presence of a well-performing surveillance system.

investigating and responding to measles outbreaks. Most recently, progress toward measles elimination in China was described in a 2014 report documenting measles elimination efforts in China during 2008–2012 and a resurgence in 2013 (*2*). This report describes progress toward measles elimination in China during January 2013–June 2019.[¶] Measles incidence per million persons decreased from 20.4 in 2013 to 2.8 in 2018; reported measles-related deaths decreased from 32 in 2015 to one in 2018 and no deaths in 2019 through June. Measles elimination in China can be achieved through strengthening the immunization program's existing strategy by ensuring sufficient vaccine supply; continuing to improve laboratory-supported surveillance, outbreak investigation and response; strengthening school entry vaccination record checks; vaccinating students who do not have documentation of receipt of 2 doses of measles-rubella vaccine; and vaccinating health care professionals and other adults at risk for measles.

Immunization Activities

China introduced measles vaccine in 1965 and implemented nationwide measles vaccination in 1978 with the start of the national Expanded Program on Immunization (EPI). In 1986, the schedule was changed to include 2 MCV doses, with the first dose given at age 8 months and the second at age 7 years (the age of administration of the second dose was lowered to 18 months in 2005, as recommended in WHO guidelines).[**] Administrative coverage, calculated as the number of vaccine doses administered divided by estimated target population, is assessed monthly at the township level (the lowest administrative level), aggregated to the national level using vaccine administration and target population data reported by EPI clinics, and reported annually to WHO and the United Nations Children's Fund (UNICEF). During 2013–2018, annual estimates of coverage with the first MCV dose (MCV1) and the second dose (MCV2) were both 99%. In 2016, among the 40,787 townships in China's 31 mainland provinces, 40,089 (98%) reported >90% MCV2 coverage by age 3 years. In 2010, a nationwide SIA was conducted, during which 103 million children received MCV regardless of previous vaccination history. Each province then used a measles risk assessment tool developed by the Chinese Center for Disease Control and Prevention (China CDC) to determine the need for additional selective or nonselective follow-up SIAs in their jurisdiction. During 2013–2018, 56.9 million children and adults were vaccinated in these follow-up SIAs. During this time, the risk assessment–based SIA target population sizes decreased approximately sixfold, from 23 million in 2013 to 3 million in 2018. To ensure that school children are protected from vaccine-preventable diseases, China has had a national requirement since 2005 that vaccination status is checked upon entry to kindergarten and primary school; children with missing vaccine doses are referred to EPI clinics for catch-up vaccination. Although the school entry record check is required, receiving missing vaccine doses is not mandatory, and unvaccinated children are not excluded from school.

Measles Surveillance Activities

Measles has been nationally notifiable since the 1950s, with aggregated data reported annually to the National Notifiable Disease Reporting System (NNDRS). In 1997, China developed a case-based, laboratory-supported measles surveillance system, initially in selected provinces and in parallel with NNDRS. The two surveillance systems were unified in 2009. Every suspected case is investigated by county-level China CDC staff members using a standardized, in-person questionnaire; outbreaks are investigated and reported by local China CDC staff members as needed. China's Meles Laboratory Network comprises 31 provincial laboratories and one national laboratory that has been accredited by WHO as a Regional Reference Laboratory since 2003[††] (*3*). Rubella case-based surveillance was integrated into the measles surveillance system in 2014. Since 2011, measles surveillance in China has met or exceeded WHO surveillance quality criteria (*4*).

Measles Incidence and Epidemiological Characteristics

From 2013 to 2014, measles incidence per million persons increased from 20.4 to 38.8; incidence subsequently declined each year, reaching 2.8 in 2018 (Table 1). Among confirmed cases reported during

[¶] Population of 1.4 billion, not including Hong Kong Special Administrative Region, Macao Special Administrative Region, and Taiwan.
[**] https://www.who.int/immunization/documents/positionpapers/en/.
[††] https://www.who.int/immunization/monitoring_surveillance/burden/laboratory/measles/en/.

2013–2018, the case count among infants aged <8 months (younger than the routinely recommended age for MCV1) decreased from 8,448 (31%) in 2013 to 532 (14%) in 2018 (Figure 1). Among the 1,839 measles cases reported in the first half of 2019, 109 (5.9%) were among infants aged <8 months, 965 (52.5%) were among children aged 8 months–14 years, and 765 (41.6%) were among persons aged ⩾15 years. During 2013–2018, the number, size, and duration of measles outbreaks decreased steadily. Until 2019, almost all (98.9%) cases that had a measles virus genotype result were found to be the indigenous genotype H1. However, in the first half of 2019, this pattern changed: 82% of genotyped measles viruses were found to be import-associated genotypes B3 or D8 (Table1) (*5*).

TABLE 1. Epidemiologic characteristics of reported measles, cases, outbreaks, and isolate genotypes — China, January 2013–June 2019.

Characteristic	Year						
	2013	2014	2015	2016	2017	2018	Jan–Jun 2019
Measles incidence, cases per million population*	20.42	38.84	31.09	18.11	4.31	2.84	1.27
No. of 31 total provinces with incidence <1 per million population	1	0	0	2	4	5	NA
No. of measles cases	27,646	52,628	42,361	24,820	5,941	3,940	1,839
Age group distribution, no. (%)							
<8 mos	8,448 (30.6)	11,193 (21.3)	10,575 (24.9)	4,652 (18.7)	950 (16.0)	542 (13.8)	109 (5.9)
8–23 mos	8,227 (29.8)	11,928 (22.7)	10,070 (23.8)	5,910 (23.8)	1,786 (30.0)	1,231 (31.2)	530 (28.8)
2–6 yrs	2,890 (10.4)	4,554 (8.6)	3,933 (9.3)	2,521 (10.2)	866 (14.6)	554 (14.1)	233 (12.7)
7–14 yrs	648 (2.3)	1,696 (3.2)	1,313 (3.1)	971 (3.9)	445 (7.5)	273 (6.9)	202 (11)
⩾15 yrs	7,433 (26.9)	23,257 (44.2)	16,470 (38.9)	10,766 (43.4)	1,894 (31.9)	1,340 (34.0)	765 (41.6)
No. of vaccine doses received by measles patients aged 8 mos–14 yrs†							
0	7,636 (64.9)	10,964 (60.3)	9,158 (59.8)	5,332 (56.7)	1,146 (37.0)	629 (30.5)	127 (14.6)
1	1,889 (16.1)	2,947 (16.2)	2,725 (17.8)	1,865 (19.8)	945 (30.5)	749 (36.4)	311 (35.9)
⩾2	724 (6.1)	1,577 (8.7)	1,453 (9.5)	1,128 (12.0)	495 (16.0)	551 (26.8)	340 (39.2)
Unknown	1,516 (12.9)	2,690 (14.8)	1,980 (12.9)	1,077 (11.5)	511 (16.5)	129 (6.3)	89 (10.3)
Laboratory confirmed (%)	96.3	96.3	96.3	96.1	85.6	96.5	92.6
Male sex (%)	59.8	56.5	56.2	55.2	57.2	57.6	56.5
No. of measles-related deaths	24	28	32	18	5	1	0
Measles deaths per million population	0.018	0.020	0.023	0.013	0.004	0.001	0
Administrative MCV2 coverage (%)	99.6	99.9	99.4	99.4	99.4	99.2	NA
No. of persons vaccinated in SIAs (million)	22.67	12.81	9.12	4.06	5.44	2.84	NA
No. of outbreaks reported§	109	283	329	230	38	37	18
No. of outbreak-related cases	436	2,080	1,847	1,235	238	158	83
Median no. of cases per outbreak (range)	2 (2–29)	3 (2–271)	2 (2–278)	4 (2–122)	3 (2–59)	3 (2–29)	3 (2–14)
Median outbreak duration, days (range)	8 (1–44)	7 (1–158)	8 (1–245)	85 (1–65)	13 (1–44)	11 (1–28)	9 (1–35)
Measles virus genotypes (no. identified)¶	H1 (2,208), B3 (3), D8 (51), D9 (47)	H1 (4,872), B3 (10), D8 (3), D9 (9), G3 (1)	H1 (3,948), D9 (1)	H1 (2,467), D8 (3)	H1 (400), B3 (1), D8 (10)	H1 (155), B3 (3), D8 (8)	H1 (24), B3 (18), D8 (91)

Abbreviations: MCV = measles-containing vaccine; MCV2 = second dose of MCV; NA = not available; SIA = supplementary immunization activity.

* Incidence for January–June 2019 is annualized.

† No. of doses of MCV received by patient as of date of measles illness onset.

§ In China, a measles outbreak is defined as the occurrence, within a 10-day period, of either two or more confirmed measles cases in a village, district, school, or similar unit or five or more confirmed measles cases in a township.

¶ https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0218782.

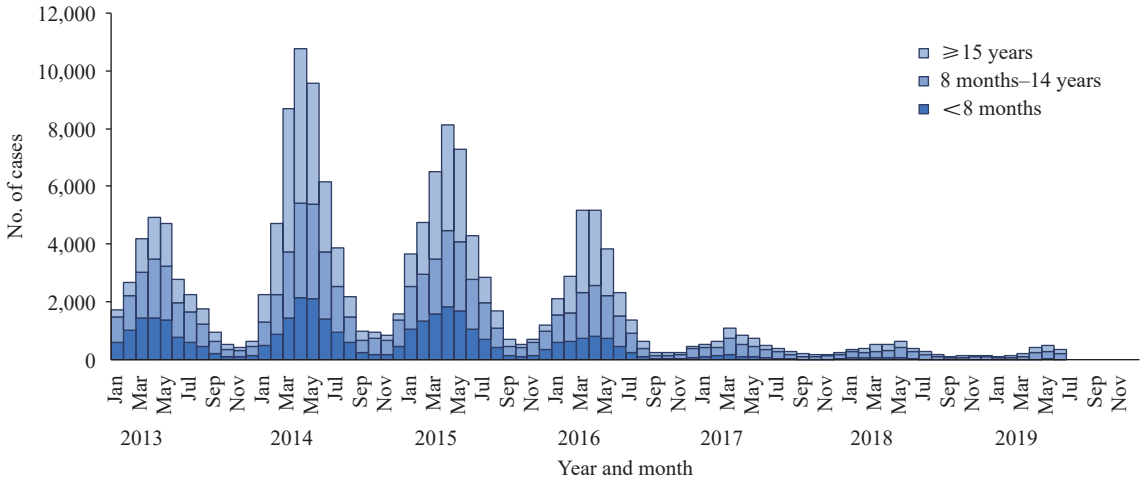

FIGURE 1. Confirmed measles cases,* by age group — China, January 2013–June 2019.

* Confirmed cases include those that are laboratory-confirmed, epidemiologically linked to a laboratory-confirmed case, or clinically compatible.

Discussion

Progress toward measles elimination in China has been considerable. Measles cases, incidence, and outbreaks were all at historically low levels in 2017 and 2018 and have decreased further through June 2019. Measles deaths are now rare in this country of 1.4 billion persons, with just one measles-associated death reported in the last 18 months.

Laboratory-supported surveillance is critical for guiding measles elimination activities and strengthening routine immunization. Outbreak investigations have identified gaps in population immunity that are addressed with follow-up immunization activities and program strengthening. The risk assessment–based SIA target population sizes markedly decreased during 2013–2018, providing indirect evidence of strengthened routine immunization service delivery.

Consultations with international partners, including CDC, WHO, UNICEF, the World Bank, the Japan International Cooperation Agency, and the Measles & Rubella Initiative[§§] have helped guide activities. Research and evaluation have also provided valuable information for measles elimination. MCVs used in China were found to be highly immunogenic in infants aged 8 months, and coadministration of Japanese encephalitis vaccine did not reduce measles seroconversion rates (*6*). In a Chinese study of risk factors for measles in children aged 8 months–14 years after a nationwide SIA, the estimated measles vaccine effectiveness among children was >95%, and being unvaccinated was the leading risk factor for infection (*7*). In addition, hospitals were important sites of measles virus transmission, and internal migration was associated with risk for measles acquisition (*7*). In a 2013 assessment of vaccination coverage in China during an outbreak following a nationwide SIA, administrative vaccination coverage might have overestimated coverage by 5%–10% (*8*). Finally, application of false contraindications to vaccination led to missed opportunities to immunize some children against measles (*9*).

Research and evaluation have led to action. In 2015, the Chinese Ministry of Health recommended measles vaccination for hospital professionals, and in 2017, China CDC and WHO hosted an international consultation to improve coverage assessment methods. Immunogenicity results provided evidence of adequate seroconversion when MCV1 is given at age 8 months, satisfying the WHO evidence requirement for routine MCV1 administration before age 9 months. EPI clinics are now directed to vaccinate migrant children after 3 months of residence.

Mathematical modeling has also proven useful. A metapopulation measles virus transmission model that estimated the basic reproduction number for measles to be 18 nationwide indicated that by 2014, the effective reproduction number was 2.3 and was <1 in 14 provinces (*10*). The model predicts that measles will

[§§] The Measles & Rubella Initiative is a partnership established in 2001 as the Measles Initiative, spearheaded by the American Red Cross, CDC, the United Nations Foundation, UNICEF, and WHO. https://measlesrubellainitiative.org/.

eventually be eliminated by the current strategy and that measles elimination can be accelerated by vaccinating middle school and high school students lacking evidence of receipt of 2 MCV doses.

The global nature of measles virus transmission is evident in the patterns of measles virus importations and exportations. China's measles surveillance system detects imported cases, and other countries have detected importations from China. For example, during January 2016–June 2019, CDC detected only one importation from China into the United States, compared with six, four, and five such importations each year during 2013–2015, respectively, supporting the understanding that cooperation among countries in fighting measles can benefit all countries.

The findings in this report are subject to at least two limitations. First, administrative coverage can be affected by inaccurate population estimates leading to under- or overestimates of coverage (*8*). Second, despite meeting WHO Western Pacific Region surveillance quality indicators, surveillance might underestimate incidence because not all measles patients come to medical attention, and some medically attended cases might not be reported.

China is approaching measles elimination, but the high transmissibility of measles virus, the size and density of China's population, and the persistence of global measles virus transmission mean that measles will continue to be detected in China for years to come. Elimination can be achieved with an updated action plan that includes ensuring sufficient vaccine supply, continuing to improve laboratory-supported surveillance and outbreak response, strengthening the school-entry vaccination record check, vaccinating students lacking documentation of receipt of at least 2 doses of measles/rubella vaccine, and vaccinating health care professionals and other adults at risk for measles. Data sharing and cooperation among countries and international organizations will continue to be critically important in the global effort to eliminate and eventually eradicate measles.

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Perspectives

The Importance of Active Surveillance in the Assessment of Vaccine Safety

Steven Black[1,2,#]

Vaccines are among the most effective public health interventions (*1*). However, vaccines can potentially cause harm. To minimize risk, proactive regulation of drugs and vaccines was implemented globally beginning in the 1950s. With new requirements for safety evaluation also came new regulations for routine post-marketing surveillance. Developments in ways to code adverse events emerged through the 1960s and 1970s and continue today, and drug and vaccine adverse event passive-reporting systems have been established in more than 100 countries. While modern vaccine pharmacovigilance includes signal-detection using spontaneous reporting, these reports can only identify possible safety signals but cannot be used to estimate risk or to evaluate a possible causal association (*2*).

Before receiving licensure, vaccines have been assessed for efficacy, quality, and safety in phase III clinical trials. These studies are traditionally viewed as the gold standard for vaccine outcomes, but they are limited in their sample size from a few hundred individuals to tens of thousands and to the types of populations included. In addition, the ability of the trials to detect rare, or very rare, events or longer-term outcomes in follow-ups of individuals is usually limited (*3*).

This is where post-marketing active surveillance based on observational studies is critical as the importance of these studies in complementing clinical trials is well-established. Observational studies in vaccine safety include a range of methodologies that compare the occurrence of outcomes of interest between people exposed and unexposed to a vaccine. Over the past 25 years, the ability to conduct observational studies and adjust for bias, most often using computerized clinical data, has evolved to a point that large observational studies can be used to assess even very rare vaccine safety outcomes. Traditional methods have used cohort and case-control designs, but more recent designs, such as the self-controlled case series, have been used in overcoming potential bias (*4*).

While large observational studies on post-licensure vaccine safety have focused on potential associations with rare events, they can also assess differences between vaccine brands and formulations and possible risks in special sub-populations such as pregnant women or HIV-infected individuals. For example with rare events, such as Guillain-Barre Syndrome, detecting a 2-fold increased relative risk with a background incidence of 1/100,000 would require a study of more than 4.7 million people. This would be impossible in a clinical trial (*5*), but by using large clinical datasets, however, such an association can be assessed. Access to clinical data that includes the potential outcomes of interest, information on the vaccination status of individuals, and the ability to link the information in these datasets using a common patient identifier is required. The same infrastructure at many sites has been used to conduct formal phase IV studies mandated by regulatory agencies.

The globalization of vaccine manufacturing has increased the need to assure that vaccines shipped globally are both safe and perceived as safe by the public. Because vaccine safety scares are now also global in scope, a global approach is warranted. To address this need, the Global Vaccine Data Network was established in 2019 with two goals: to facilitate global collaborative studies of vaccine safety to increase their statistical power and to assist in developing infrastructure for the conduct of active surveillance observational studies in key areas of the world. The GVDN network is based in New Zealand and includes scientists from 17 countries, including two from China, with expertise in conducting large observational studies of vaccine safety. At present, the network is developing a protocol to assess the risk of Guillain-Barre Syndrome following the influenza vaccine and to assess possible genetic risk factors for Guillain-Barre disease. Because of the global scope of the network, the study will be able to compare risk between different types of influenza vaccines and in different populations.

In China, there has been a dramatic increase in

vaccine manufacturing for both the domestic and international markets, and there is increasing recognition that infrastructure to conduct state-of-the-art active surveillance of vaccine safety using phase IV observational studies is vital for maintaining public confidence and to meet international regulatory standards and expectations. Fortunately, in China there are locations with comprehensive computerized clinical datasets that include both clinical outcomes as well as vaccination status. This opens the possibility of using sentinel active surveillance in these select areas should a decision be made to develop this infrastructure. Such a sentinel approach was used by US CDC in establishing the Vaccine Safety Datalink (VSD) project in the US that now routinely conducts vaccine safety studies of all new vaccines used in the US (*3*). The VSD has conducted numerous vaccine safety studies to address concerns raised through passive surveillance and issues of concern to the public including autism following MMR vaccine, multiple sclerosis following hepatitis B vaccine, and chronic arthritis following rubella vaccine (*6*). The active surveillance studies have been able to reject each of the original concerns.

In summary, the assessment of vaccine safety post-licensure requires both passive reporting systems for signal detection and active surveillance based upon observational studies for assessment of possible associations. The globalization of vaccine manufacturing and the emergence of many manufacturers in China and other countries means that such assessments can no longer be done exclusively in North America or Europe where such studies have traditionally been conducted. Because of the internet, vaccine safety scares and concerns spread widely and now require a coordinated and rapid global response to avoid declines in vaccine uptake and resulting increases in vaccine preventable diseases. The availability of computerized clinical data in many countries and this need for a global coordinated response has fostered the development of the Global Vaccine Data Network. Within China, the components and expertise exist to develop an active surveillance system for vaccine safety post-licensure. Developing this infrastructure would help manufacturers meet phase IV regulatory requirements to assess vaccine safety and would help appropriately address vaccine safety concerns in China.

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Perspectives

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.ants.

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, Heamophilus 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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