

# 16

## National Initiatives and Revisions to Preventive Vaccination Policies Leading to Better Prevention

### Situation

Vaccines play a major role in decreasing the incidence of infectious disease, enhancing the quality of life, and in many cases also resulting in economic benefits. As described in the “Vaccine Business Vision,” vaccines are globally recognized as highly cost-effective.

Many new vaccines have been approved in Japan recently and the number of vaccines covered by the Japanese national immunization program has increased gradually. In addition, the government of Japan deserves credit for developing the “Basic Plan for Vaccination” as a national medium- and long-term strategy. However, even among the four policy goals that were designated as an immediate goal in the Basic Plan, three are still in the beginning phase of discussion: 1) raise regular vaccination rates; 2) develop new vaccines; and 3) enhance public communications and education. In addition, there is a mountain of outstanding issues. For example, the evaluation process deciding which newly developed vaccines are introduced into the national vaccination program is still unclear. In some cases, there is no public funding or there are inconsistencies in public funding levels in regions and municipalities across the nation.

Furthermore, the public is not receiving adequate and accurate information with regard to the benefits of vaccination or the potential risk of side effects, which is one of the major causes of the troubling vaccine access gap in Japan. If an individual or family is financially secure and receives the proper information, they will be able to protect themselves from preventable diseases with the use of vaccines. However, individuals and their families without financial security, or those who are financially stable without the proper information, will not receive the benefits of vital vaccines that are widely used around the world.

In addition, those citizens who are not adequately protected by vaccines as a group

may suffer a dramatic increase in the prevalence of the relevant disease during outbreaks. For this reason, there is a high probability that a public health response will be required, resulting in financial burdens on the healthcare system which far outweigh the cost of vaccination itself.

### Current Policy

Based on the Preventive Vaccination Law revised in April 2013, the official preventive vaccination plan for Japan, the “Basic Plan for Vaccination” established in April 2014, stated clearly that Vaccine Preventable Diseases (VPD) should be prevented by vaccination. However, discussions regarding many issues in the Basic Plan have yet to begin. The national vaccination program based on the Preventive Vaccination Law specifies that vaccines for Category A diseases are almost all provided free of charge, while partial subsidies for fees related to vaccination are provided for Category B disease vaccines. By contrast, so-called voluntary inoculations are not covered by public funds. In addition, an “Advisory Panel on Immunization and Vaccination Sub-council” was established in April 2013 to discuss adding newly approved vaccines to the national immunization program. However, almost two years have passed and neither the schedule nor the review process have been made clear and discussions have not progressed from an operational standpoint.

### Progress in policies over the past year:

#### Some improvement

“Elimination of vaccine-gap” is one of the prioritized issues in the Basic Plan. We have seen some progress which addresses this issue: Varicella and adult pneumococcal vaccine (23-valent polysaccharide vaccine) were added to the national immunization program in October 2014. It seems too early to say how statistically impactful the program changes have been on the vaccination rate of these two vaccines, but the number of vaccinations has been reported to have increased significantly. In addition, the “Advisory Panel on Immunization

and Vaccination Sub-council” concluded to recommend adding the hepatitis B vaccine into the national vaccination program in January 2015. As for rotavirus, preparations for scientific discussion are continuing.

Furthermore, in 2014, scientific discussion and investigation about whether newly approved vaccines should be added to the national immunization program began immediately after the regulatory approval for the following vaccines: meningococcal vaccine, DTP (diphtheria, tetanus, pertussis)-IPV (soak) 4-valent vaccine, and pneumococcal vaccine (13-valent conjugate vaccine) for adults.

The ACCJ and EBC highly appreciate such governmental efforts to improve vaccination policy in this way. However, concerns remain about the following issues.

- There is no clear schedule for the evaluation of whether vaccines currently designated as “voluntary vaccination status,” such as vaccines for mumps, rotavirus, and pneumococcus infectious diseases for adults (PCV13), could be given National Immunization Status.
- The rules and processes for reviewing or evaluating many pre-defined issues identified in the “Basic Plan for Preventive Vaccination” are unclear and there are many uncertainties about whether the evaluation outcomes would be feasible to implement.
- Under the current system, in general municipalities bear immunization costs and fees in general, though there are no clear rules or strategies for securing permanent budgets to fund the national immunization program, despite the designation of an increasing number of vaccines in the future.
- As more new vaccines are added to the national vaccination program, it has become apparent that there are significant issues related to how to deal with disease surveillance, how to analyze adverse

effects and how to review and evaluate the outcomes or efficiency of the national vaccination program. There are no clear systems or processes set up for proceeding with this important evaluation and analysis necessary to secure governance and control systems to effectively manage the national immunization program.

- As an example, active promotion of the routine vaccination of HPV vaccines has been discontinued since June 2013 due to uncertainties regarding the causal relationship of a small number of reported adverse reaction cases with HPV vaccinations. Rapid evaluation of this type of issue by specialists was required. However, these evaluations and investigations take a great deal of time if there is no established data base or system to collect epidemiological and background information, such as the vaccination records. As of March 2015, the process to resume active promotion is still unclear. The resulting increased infection risks and confusion among medical personnel, local governments and parents are of great concern.
- Although the number of vaccines in the national vaccination program has increased, national and local governments cannot provide appropriate information to the public effectively and efficiently, especially clear risk/benefit information of vaccination. In addition, information provision regarding vaccination programs relies heavily on municipalities, which may lead to a digital divide, misunderstanding and confusion among the public because of inconsistencies in the quality and quantity of information about vaccines provided by different municipalities.

## Recommendations

- Prepare a detailed table providing information on who will be responsible for what sort of actions or evaluations by which deadlines to establish a comprehensive system to evaluate results regarding individual items in the “Basic Plan for Vaccination.”
- Have the government of Japan fully subsidize all vaccines should be completely subsidized by the government. Furthermore, build an infrastructure to enable permanent funding of this program.
- Following new vaccine approvals in accordance with the Pharmaceutical Affairs Law, lay out clear rules and schedules to quickly incorporate these vaccines into the national vaccination program.
- Promote global harmonization of related regulations and standards to facilitate rapid Japanese approval of vaccines used worldwide.
- Strengthen and improve epidemiological research to promote understanding of the financial and social burden imposed by infectious diseases, to measure the preventive efficacy of inoculation against relevant diseases, and to evaluate the incidence of vaccine adverse reactions and their influence.
- Public understanding is quite important for the promotion of vaccination. Therefore, increase the national budget for information provision and advocacy activities that enable the central government to conduct continuous communication to the public. In addition, the government should establish a framework, standardized processes and organization for orchestrating risk-communication in emergencies.

## Case Study: U.S. National Adult Immunization Plan

In the United States, the National Vaccination Plan, a 10-year plan for vaccines and the preventive vaccination enterprise was

established. The plan was revised in 2010. The plan states the policy regarding the research and development, safety, provision of information, vaccination rates, and supply of vaccines and strategies for the promotion of global vaccination and prevention, have led to various results.

However, in the review process, it was found that vaccination coverage levels among adults were not on track to meet 2020 targets and are quite low compared to the levels among children. As a result of discussion among the stakeholders, the National Adult Immunization Plan (NAIP) was drafted as a national adult vaccination strategy.

Barriers that were highlighted for the promotion of vaccination among adults:

- Lack of coordination of adult immunization activities across all stakeholders, including multiple healthcare providers for adults
- Lack of integration of vaccines into adult medical care
- Lack or underuse of administrative systems for documenting vaccination histories and identifying patients who are due for vaccinations in medical records
- Skepticism regarding vaccine safety and effectiveness
- Inability to pay for vaccination as a result of lack of insurance or variable coverage for recommended vaccinations across health plans
- Provider concerns about reimbursement and vaccine administration fees paid by health insurers, which discourages some providers from stocking all adult vaccines
- Lack of public knowledge regarding the adult immunization schedule and the risks and consequences of vaccine-preventable diseases; lack of awareness that adults are supposed to receive more than influenza vaccines
- Lack of and/or weak recommendations by health care providers
- Limited use of evidence-based strategies to improve vaccine uptake, such as reminder-

- recall and related systems
- Conflicting and inaccurate information about immunizations in mass media

Detailed activity plans and a roadmap are established for each goal.

**Four NAIP Goals Developed to Help Address the Above Barriers:**

Goal 1:

Strengthen the adult immunization infrastructure.

Goal 2:

Improve access to adult vaccines.

Goal 3:

Increase community demand for adult immunizations.

Goal 4:

Foster innovation in adult vaccine development and vaccination-related technologies.

In this way, the U.S. government practices the PDCA cycle for promotion of vaccination program: Plan and Do National Vaccination Plan, Check progress, and take required Action (development of NAIP).

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**References**

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2. U.S. Department of Health and Human Services website page on the National Vaccine Plan, accessed Feb 24, 2015. [http://www.hhs.gov/nvpo/vacc\\_plan/](http://www.hhs.gov/nvpo/vacc_plan/)
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4. Draft - The National Adult Immunization Plan. U.S. Department of Health and Human Services website page, accessed Feb 24, 2015.
5. [http://www.hhs.gov/nvpo/national\\_adult\\_immunization\\_plan\\_draft.pdf](http://www.hhs.gov/nvpo/national_adult_immunization_plan_draft.pdf)

## 16. Vaccination Basic Plan defines 8 items to improve and enrich Japanese vaccination system

### Vaccination Basic Plan

1. Establish basic direction for comprehensive plans and measures for promoting vaccination
2. Clarify roles and responsibilities of national, prefecture and municipal government officials and their administrative partners in a vaccination program
3. Define objectives to evaluate effectiveness and efficacy of comprehensive plans and measures for promoting vaccination
4. Identify critical success factors to execute comprehensive plans and measures for promoting vaccination
5. Define basic principles to execute plans and measures for accelerating research and development of innovative vaccines, and for securing supplies of commercialized vaccines
6. Establish fundamental items to promote measures for improving efficacy and safety of a vaccination program
7. Set directions how to proceed with international alliances and collaboration on vaccination initiatives
8. Reveal other important items to affect comprehensive plans and measures for promoting vaccination

HSB Notification No.0328/1, March 28, 2014 "Basic Plan for Vaccination"

## 16. Delayed practical discussion on "Vaccination Basic Plan", even on items designated as "Immediate goals"

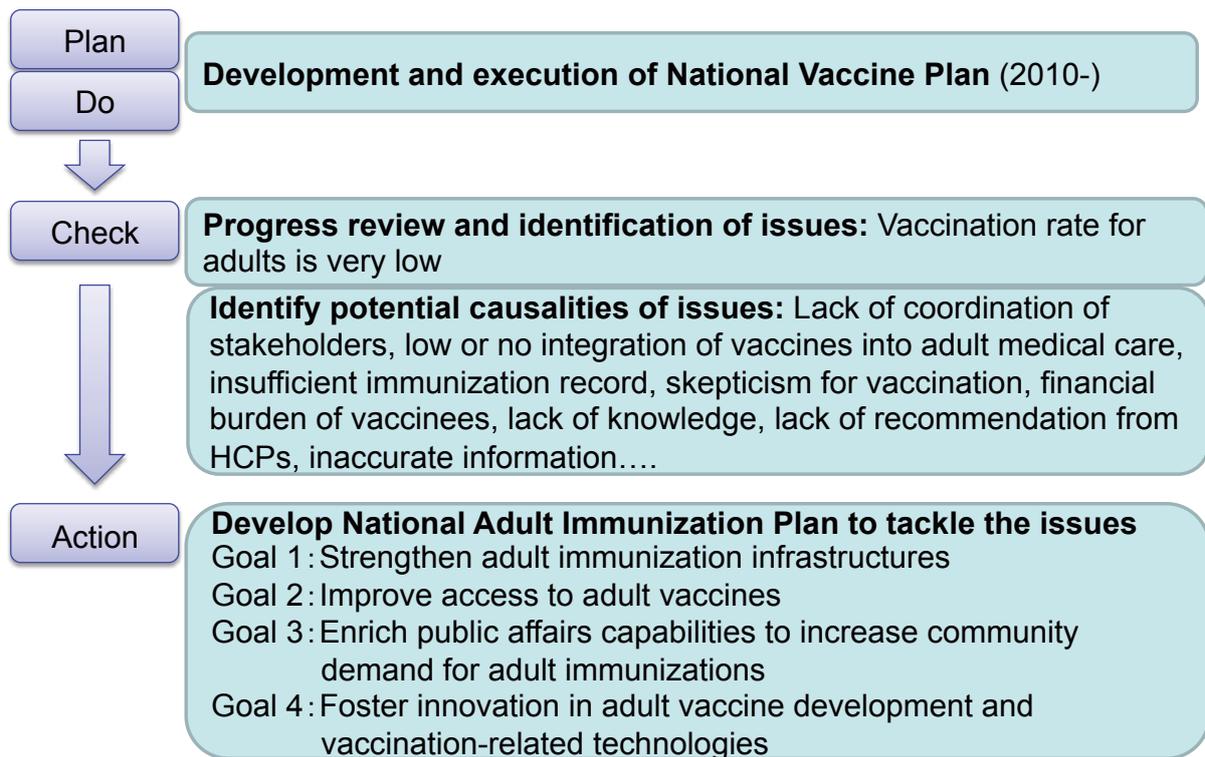
Item	Progress	Status
Eliminate vaccine gap	△	8 vaccines had been evaluated as eligible for the national vaccination program: five vaccines were chosen to be introduced into the program; one vaccine was officially recommended*1
Raise regular vaccination rates	×	No particular discussion started yet
Develop new vaccines	△	Identified prioritized vaccines to be developed at the discussions*2, but no practical action to proceed in their development has started yet
Enrich public affairs and education initiatives to public	×	No particular discussion has started yet

\*1 : Vaccines introduced into national program: HPV, Hib, pediatric pneumococcal(PCV13), varicella, adult pneumococcal(PPSV23)  
 Vaccine recommended for national program: hepatitis B  
 Vaccines which evaluation are ongoing: mumps, rotavirus

\*2 : combination vaccine based MR (Measles/Rubella) , combination vaccine based DTP-IPV, New type influenza vaccine (e.g. nasal type),  
 Norovirus vaccine, RS virus vaccine, Herpes Zoster vaccine

HSB Notification No.0328/1, March 28, 2014 "Basic Plan for Vaccination"

## 16. US Case Study: National Adult Immunization Plan has PDCA Cycle to Evaluate and Refine its Implementation and Execution



[http://www.hhs.gov/nvpo/national\\_adult\\_immunization\\_plan\\_draft.pdf](http://www.hhs.gov/nvpo/national_adult_immunization_plan_draft.pdf)