Health and Global Policy Institute (HGPI)
Immunization and Vaccination Policy Project

Reshaping Japan's Immunization Policy for Life Course Coverage and Vaccine Equity:

Challenges and Prospects for an Era of Prevention and Health Promotion

Contents

Background

Vaccines have been called one of the “greatest inventions in medical history” and immunization is one of the most cost-effective methods of infectious disease control. While progress in immunization policies has mainly been centered on infancy and early childhood, these policies have made great contributions to human health and socioeconomic stability. However, the range of vaccine-preventable diseases (VPDs) is vast, and addressing VPDs will require immunization systems that cover all life stages from infancy, childhood, adolescence, adulthood, and through old age. A life-course approach to immunization is also emphasized in the Immunization Agenda 2030 (IA2030) presented by the World Health Organization (WHO). A life-course approach will also be essential in achieving Japan’s goals of creating a society of health and longevity as well as achieving prevention and health promotion. However, the immunization system in Japan has been built in accordance with the Immunization Act of 1948, and it is gradually growing more difficult to address emerging challenges like demographic transition, financial constraints, and technological innovation. In April 2025, the National Immunization Plan[1] was revised for the first time in over eleven years. While we look forward to the steady implementation of that plan in the future, responding to increasingly complex changes in society will require policy discussions to review the Immunization Act and the design of the immunization system down to its foundation. Given this context, to further increase momentum for discussions that go beyond the recent revision, Health and Global Policy Institute (HGPI) offers the following discussion points to help direct the long-term discussions needed for the future of immunization and vaccine policy.

Discussion Point

01

Conditions for vaccines to be included in the routine immunization schedule must be clarified and the positioning of category B and related diseases in the Immunization Act must be reviewed.

Japan's immunization system operates within two frameworks: routine vaccinations (or statutory vaccinations) provided in accordance with the Immunization Act; and voluntary vaccinations (or non-statutory vaccinations) that are not stipulated by that Act. Recipients can access routine vaccinations free of charge or at low cost through public funding from the national and local governments. Vaccinations are also classified into two categories: category A diseases[2] for mass prevention and the prevention of serious illness and category B diseases[3] for individual prevention (hereinafter, "routine category A" and "routine category B"). As of April 2025, the routine vaccination schedule includes vaccines for a total of 18 diseases (14 routine category A diseases and 4 routine category B diseases). As for voluntary vaccinations, they target diseases not covered by the routine vaccination schedule and are not subject to legal requirements regarding who should be vaccinated or when. All voluntary vaccinations are administered at the discretion of recipients or their guardians, and at their own expense.

In this context, shifting vaccines from the voluntary to routine framework (in other words, adding items to the routine vaccination schedule) has expanded vaccination coverage and made great contributions to human health. For example, after the varicella vaccine was included on the routine schedule in 2014, coverage soared from around 30% to 40% to over 95%, significantly reducing infections and complications.[4,5] However, it took almost 30 years for this shift to occur, partially because of uncertainty regarding criteria on qualifying for the routine schedule. Standards for routine and voluntary vaccinations vary according to the era or social conditions,[6] and those standards must be updated

regularly to keep pace with advances in scientific knowledge. The reasons why some vaccines are categorized as voluntary also vary. It is precisely for this reason that clarifying the conditions for determining the inclusion of a vaccine on the routine schedule and establishing a transparent and suitable review process is an urgent matter for contributing to human health and socioeconomic stability.

While routine category A vaccines are generally provided free of charge and have achieved coverage of 90% or greater, routine category B vaccines incur out-of-pocket expenses, and coverage is sometimes under 50%.[7] There are also examples of routine vaccines that have coverage that is equal or comparable to voluntary ones, such as the pneumococcal vaccine for older adults, which is a routine category B vaccine that had 33.5% coverage in 2022.[8] When voluntary vaccines are included on the routine schedule, they can be placed under either category. While various items have been examined over the long history of immunizations in Japan, by returning to the basic principle of Japan's immunization policy, which is "to prevent infections that can be prevented through immunization and vaccination," it may be necessary to reexamine how to best structure the current Immunization Act, particularly the positioning of routine category B vaccines and their administration.

Discussion Point

02

The national government and local governments must unite in expanding immunization financing to correct disparities in immunization opportunities among municipalities or by area of residence.

Routine vaccination programs are within the jurisdiction of municipal governments, and each municipality is responsible for implementing them. Municipal governments fund these programs through the local allocation tax, which is a general revenue source provided each fiscal year.[9] However, the use of the local allocation tax is left to the discretion of municipal governments, who can allocate budgets based on their respective policy priorities. This means funding allocated to routine vaccination programs are not always sufficient, making it difficult for them to be implemented in a stable and continuous manner. This ultimately results in disparities in immunization opportunities among municipalities.

The key issue for routine category A programs in municipalities is continuity. The national government covers approximately 90% of costs for routine category A vaccines, and municipal governments cover almost all of the remaining 10% voluntarily and with public finances. As a result, in principle, citizens can receive vaccines free of charge. However, there is no guarantee that every municipality can always cover the remaining 10%. The Basic Act on Child and Maternal Health and Development[10] guarantees every child “the right to receive scientifically proven medical care regardless of their place of residence.” In practice, routine category A vaccines target infancy and early childhood, so further action will be necessary.

The main issue related to routine category B is that there are significant differences in out-of-pocket costs among municipalities. The national government covers only about 30% of the cost of routine category B vaccinations, while municipal governments and citizens cover the remaining 70%. However, how that portion is split among out-of-pocket payments from citizens and public funds from municipalities is completely different from one municipality to another. According to an independent survey from HGPI, there are even wide gaps in out-of-pocket costs among prefectural capitals. As for specific examples of the significant variation in out-of-pocket cost among municipalities, it ranges from 800 yen to 2,300 yen for regular category B influenza vaccination and from 1,500 yen to 5,000 yen for pneumococcal vaccination.[11] Even though vaccinations are generally not covered by the Health Insurance Act, it is by no means fair for out-of-pocket costs to be determined entirely by the municipality where one lives without any sort of income-based adjustment.

Furthermore, for both routine category A and routine category B, people who are vaccinated in municipalities where they are not registered as residents (such as students, expectant mothers who temporarily move back in with parents for childbirth, their infants, or residents of protective institutions or long-term care facilities) may be required to pay co-payments. It will also be necessary to expand human resources responsible for conducting municipal vaccination programs in order to provide people receiving vaccines with thorough support.

At the very least, as routine vaccinations are statutory vaccinations, the national government should provide broad-reaching support based on the purpose of the Immunization Act, which is to "prevent the outbreak and spread of disease and contribute to maintaining the health of the people." The national government should increase the ratio covered by national public expenditures, set aside financial resources specifically for immunization (e.g., national treasury contributions, national subsidies), redefining measures from "within the jurisdiction of local governments" to "legally-entrusted administrative duties" (which are duties that are officially entrusted to prefectural or municipal government by the national government, or to municipal governments by prefectural governments), and unite with local governments in efforts to expand financing for vaccination programs and related efforts. The diseases targeted by routine vaccinations are all designated by law or ministerial ordinances, leaving municipalities little discretion, and related duties have already taken on the nature of legally-entrusted administrative duties. While from the viewpoint of decentralization it is desirable that "assigning new legally-entrusted administrative duties is avoided to the greatest extent possible[12]", reflecting on the purpose of the Immunization Act, it becomes clear that the response should be tailored to actual circumstances surrounding vaccination programs. It will be necessary to consider options in a flexible manner and prepare the groundwork for municipal governments to maintain stable vaccination programs.

It must be noted that the indicated ratios of the burden borne by public finances from the national government only serve as the basis for calculating local allocation tax amounts, and that these calculated amounts differ from the amounts that are actually provided to local governments. When discussing total immunization finances, it will be necessary to clarify unit costs for immunizations (which is the sum of vaccine costs and immunization consignment fees) to serve as the basis for calculating local allocation taxes.

Discussion Point

03

Correcting age-based disparities in immunization opportunities will ultimately require a full redesign of the immunization system that takes precedents set by local governments into account.

As discussed above, routine vaccinations fall into two categories: routine category A, where emphasis is placed on preventing the spread of infectious diseases; and routine category B, where the aim is to prevent the onset and progression of diseases for individuals. However, in practice, routine category A is centered on preventing acute infectious diseases in infants and young children and routine category B is centered on preventing infections on the individual level among senior citizens. As a result, opportunities for immunizations in adolescence and adulthood are not being given adequate consideration. Examples of vaccines that may fall under these categories (for group prevention or individual prevention) but are voluntary include travel vaccines needed for international travel; vaccines needed for training or employment in healthcare, welfare, or educational institutions; and tetanus revaccination for injury or trauma prevention. As these are all voluntary vaccines that are not required by law, in principle, all costs are paid out-of-pocket.

To improve this situation, local governments in certain regions have introduced systems that provide subsidized vouchers for voluntary vaccinations. In those systems, vouchers can be used once per year to provide eligible people from infancy to high school age any voluntary vaccination they need at that time. This allows them to receive a fixed subsidy of an amount that is within the range set by the local government, regardless of disease category. In another municipality, the local council is leading an initiative to expand subsidies for voluntary vaccinations (in which vaccinations are provided as statutory vaccinations and treated as legally-entrusted administrative duties). While referring to innovative examples from each municipality like those described here, it will be necessary to advance nationwide efforts to correct all disparities in immunization opportunities in the future.

However, it will be necessary to only consider these measures as temporary ones. This is because unlike routine vaccinations, adverse health effects due to voluntary vaccinations are not covered by the national government's Relief System for Injury to Health with Vaccination. While there is of course a separate relief system, the compensation it provides can vary,[13] and there are limits to how much can be covered by liability insurance voluntarily purchased by municipal governments.[14] Ultimately, expectations are high for the national government to proactively redesign and optimize the immunization system to be based on the life course approach without relying on the autonomy of municipal governments or their financial resources.

Discussion Point

04

Revaccination support and similar measures must be expanded to address disparities in immunization opportunities caused by disease risk.

Only a limited number of municipalities currently provide revaccination support for patients who lose specific immunity after medical procedures like hematopoietic stem cell transplantation. As of 2018, the percentage of municipalities nationwide operating systems subsidizing revaccinations was 5.2%, or 89 municipalities. Since 2018, that number has more than tripled,[15] but eligibility for those systems has gone mostly unchanged, and availability is limited almost exclusively to minors.[16] However, the annual number of hematopoietic stem cell transplantations has reached approximately 6,000, and more than half of them are performed on people age 50 years and over.[17,18] The lack of support results in triple inequality based on residence, age, and disease risk.

Systems subsidizing revaccinations are operated as independent programs from each local government, and the scope of coverage varies based on each municipality's autonomy and financial circumstances. From the perspective of the life-course approach, we hope to see coverage expanded to include adults and senior citizens in addition to minors. Considering the scope of each group eligible for subsidies, expanding coverage will have a limited impact on national and local finances, and the nationwide expansion of such programs is also well within the realm of possibility. Hematopoietic stem cell transplantation is not the only treatment that results in immunity loss; it can occur due to a wide range of treatments including anticancer drug therapy or other types of transplantation. Immunity also declines due to aging. Due to this, rather than haphazardly expanding revaccination support and other relatedprograms, it will be important to identify the scope of "vaccinations provided for therapeutic purposes or as extensions of treatment" and "ordinary vaccinations" in medical and scientific terms and to mount a systematic response through a combination of the Health Insurance Act, the Immunization Act, and related laws.

Discussion Point

05

The functions of the Immunization and Vaccine Subcommittee and similar groups must be reinforced, and the immunization system must undergo evidence-based evaluation.

In their capacity as the National Immunization Technical Advisory Group (NITAG), the Health Sciences Council of the Subcommittee on Immunization and Vaccination and related committees or subcommittees (hereafter, "subcommittees") have played a key role in domestic immunization policy. Japan joined the Global NITAG Network in 2024 and is now further reinforcing the functions of subcommittees. While making proactive use of global expertise obtained through the Global NITAG Network and data held by private companies, in the future, it will be necessary to perform more specialized, scientific, and timely evaluations of vaccines starting after the submission of regulatory applications. There are particularly high expectations for collaboration among industry, government, academia, and civil society to generate data on effectiveness and safety. To ensure success, steps must be taken to accelerate and streamline data collection and analysis by digitizing vaccination records and adverse reaction monitoring for both routine and voluntary vaccinations and by reinforcing surveillance.

Furthermore, as covered in Discussion Point 1, to contribute to human health and socio-economic stability, it is urgent that Japan first clarify the conditions for adding vaccines to the routine vaccination schedule and establish a transparent and valid review process. In addition to vaccine effectiveness and safety, another item currently being examined during discussions on routine vaccinations at subcommittees is the health economics of vaccines. When examining this topic, analyses are conducted with the assumption that all costs of administering vaccines are covered by public funds, but right now, the national govern-

ment covers approximately 90% of these costs for routine category A vaccines and approximately 30% for routine category B vaccines. In other words, even when an analysis determines that a vaccine is cost effective when the national Government pays 100% of the cost, in reality, the proportion of the cost paid with public funds from the Government is less than 100%. This gap has been brought up in fact sheets in the past,[19] and the fact that this assumption leads to a somewhat conservative analysis from the perspective of the Government has also been pointed out.[20]

On the other hand, because the healthcare cost savings achieved by vaccination programs are considered in a comprehensive manner that takes into account both public funding from the government and out-of-pocket payments, some believe that the current method of analysis is, to a certain degree, consistent. In the future, it will be necessary to give sufficient consideration to how to best implement immunization policies and incorporate more diverse values (such as productivity losses for patients or caregivers, or lower QOL for caregivers). There are also high expectations for appropriateness assessments to be conducted on policies that evaluate cost-effectiveness for vaccines after inclusion on the routine schedule that take into account the fact that public burdens or immunization unit costs (the sum of vaccine costs and immunization consignment fees) vary by municipality. It will also be necessary to view immunization policies in terms of equity and various other new perspectives in addition to effectiveness, safety, and cost-effectiveness, and to apply a suitable PDCA cycle[21] related to immunization policies.

Discussion Point

06

Policy discussions must be advanced through multi-stakeholder discussions that consider immunization policy in terms of the overall health system.

In addition to the Immunization Act, domestic immunization policy is deeply rooted in several laws and plans such as the Local Autonomy Act, the Local Allocation Tax Act, the Act on Assurance of Medical Care for Elderly People (including plans to optimize healthcare costs), the Health Promotion Act (Health Japan 21), and the Basic Act on Child and Maternal Health and Development. However, past policy discussions have mainly taken place within the framework of subcommittees. Such subcommittees are established in accordance with the Immunization Act and related laws,[22] and their roles and duties are clearly defined. This results in a natural tendency for their policy discussions to be limited to the scope of the Immunization Act. In other words, it is difficult for those discussions to address the nature of the Immunization Act because it is foundational to the establishment of the subcommittee, or for those discussions to be held with the premise that changes will be made to the design of the system in order to examine items from Discussion Point 1, like the review of routine category B or the overall categorization system. It is also difficult for these subcommittees to discuss consistency with other laws and regulations, or fundamental issues related to the entire health system.

Antibody preparations have also emerged in recent years and can be expected to be almost as effective as vaccines. However, the scientific nature of antibody preparations does not always fully conform to the legal definition of immunization, which is to “produce an immune response to a disease,” so the manner in which current laws relate them will require thorough examination. As antibody preparations are pharmaceutical products,

they must also conform to the Health Insurance Act (namely, the medical service reimbursement and drug pricing systems). However, the basis of that Act (or, those systems) is “benefits for medical treatment.” Japan’s health system operates under the principle of universal health coverage and does not provide sufficient incentives for prevention or preventive medicine. Given this complex situation, there are strong hopes for subcommittees to advance evidence-based assessments of the immunization system while taking a fresh look at the positioning of immunization policy in Japan’s overall health system.

To facilitate such developments, it will be necessary for comprehensive multi-stakeholder discussions to be held with all related government agencies and departments including the Ministry of Health, Labour and Welfare; the Ministry of Internal Affairs and Communications; the Ministry of Finance; the Ministry of Education, Culture, Sports, Science and Technology; and the Children and Family Agency; as well as with academia in areas such as medicine, law, education, and public health; and with officials representing local governments or serving in local finance, healthcare professionals, industry representatives, members of national and local legislation, and citizens. While collaborating closely with these multi-stakeholders, the national government should actively illustrate a vision for immunization policy so an immunization system that contributes to human health, socioeconomic stability, and sustainability can be designed and utilized.

Works referenced

1 Formally, the “Basic Plan for Vaccination.”

2 Category A diseases: rotavirus, diphtheria, tetanus, pertussis, acute myelitis (polio), Hib infection, pneumococcal infection in infants, hepatitis b, tuberculosis (BCG), measles, rubella, varicella, Japanese encephalitis, and human papillomavirus (HPV).

3 Category B diseases: seasonal influenza, Coronavirus Disease 2019 (COVID-19), adult pneumococcal infections for senior citizens, and shingles.

4 National Institute of Infectious Diseases, Japan (NIID). “Varicella Vaccine Fact Sheet (July 7, 2010 ed.).” https://id-info.jihs.go.jp/relevant/vaccine/topics/140/Varicella_20100707.pdf. Last retrieved on April 25, 2025.

5 NIID. “Varicella Outbreak Trends after Introduction of Routine Varicella Vaccination: Infectious Disease Trend Survey (Week 26, 2021).” https://id-info.jihs.go.jp/niid/ja/varicella-m/varicella-idwrs/10892-varicella-20220113.html. Last retrieved on April 25, 2025.

6 In 1948, routine vaccinations were provided for a total of 12 diseases: smallpox, diphtheria, typhoid fever, paratyphoid, pertussis, tuberculosis, typhus, plague, cholera, scarlet fever, influenza, and Weil’s disease. Among these, there are 14 diseases for which routine vaccinations were not provided at the time but are on the routine schedule as of April 2025.

7 Ministry of Health, Labour and Welfare. “Number of people receiving routine vaccinations.” https://www.mhlw.go.jp/topics/bcg/other/5.html. Last retrieved on April 25, 2025.

8 NIID. “Findings of Mump Vaccination History Survey in Recent Years – National Epidemiological Surveillance of Vaccine Preventable Diseases (NESVPD), FY2015.” https://id-info.jihs.go.jp/niid/ja/typhi-m/iasr-reference/6830-440r09.html. Last retrieved on April 25, 2025.

9 Excludes 1 prefectural and 82 municipal governments that are not granted the local allocation tax (as of 2024).

10 Officially, the “Act On Promoting Comprehensive Measures for the Seamless Provision of Child Care, Medical Care for Health and Development, and Other Necessary Forms of Care to People Currently in the Growth Process, Their Guardians, and Expectant and Nursing Mothers” (provisional translation provided by HGPI).

11 According to an independent desk study conducted by HGPI on real-world circumstances in the prefectural capitals of 47 prefectures. The study was limited to municipalities where out-of-pocket costs for individuals were disclosed as of December 2023, and excluded municipalities for which information was limited to that regarding subsidies or deduction amounts.

12 The Supplementary Provisions of the Omnibus Decentralization Act, Article 250.

13 Health harm from voluntary vaccinations is covered by the Pharmaceuticals and Medical Devices Agency (PMDA) Relief System for Adverse Drug Reactions, the same system for health harm from ordinary pharmaceuticals.

14 Many municipalities have their own liability insurance in case of the unlikely event of a vaccine injury. In particular, for voluntary vaccinations provided under legally-entrusted administrative measures, after establishing provisions on compensation for vaccine-related health harm and similar topics, some municipalities purchase additional, dedicated insurance like the Japan Association of City Mayors Vaccine Injury Compensation Insurance or the National Association of Towns and Villages Comprehensive Compensation Insurance.

15 Saitama Prefecture. “Subsidy programs in 301 municipalities nationwide: Regular meeting of June 2020, General Questions and Answers (Full text).” https://www.pref.saitama.lg.jp/e1601/gikai-gaiyou/r0206/k020.html. Last retrieved on April 25, 2025.

16 MHLW. The 26th Meeting of Health Sciences Council of the Subcommittee on Immunization and Vaccination on the Basic Policy on Immunization. “Reference 3: Survey findings: Status of revaccination support for immunity loss due to medical procedures such as bone marrow transplantation, and handling of routine vaccinations provided outside of area of residence.” https://www.mhlw.go.jp/stf/shingi2/0000210542_00004.html. Last retrieved on April 25, 2025.

17 The Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT) and the Japanese Society for Transplantation and Cellular Therapy. “Hematopoietic Cell Transplantation and Cellular Therapy in Japan 2023, FY2023 National Survey Report.”

18 JDCHCT. “FY2023 National Survey Report (Separate volume).”

19 Fact sheets were created to enable the scientifically sound examination or evaluation of national immunization policies for diseases and vaccines that were not identified as routine vaccinations in the Immunization Act. Their creation was centered around NIID (now the Japan Institute for Health Security) and generally included: (1) basic knowledge for the disease (clinical findings, epidemiological information, etc.); (2) vaccine effectiveness; (3) vaccine safety; and (4) objective, trustworthy, and recent scientific findings on cost-effectiveness.

20 NIID. “Shingles Vaccine (Second Ed.) June 20, 2024 Version (Partially revised November 1, 2024).” https://id-info.jihs.go.jp/relevant/vaccine/topics/140/Zoster_20241101.pdf. Last retrieved on April 25, 2025.

21 The PDCA cycle is a method of achieving goals, enhancing operations, or increasing efficiency through the repeated application of a four-step process of plan–do–check–act.

22 These include the Act on the Establishment of the Ministry of Health, Labour and Welfare (Article 6), the Health Science Council Ordinance (Article 5), and the Immunization Act (Articles 13, 15, 24).

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Experts and specialists who participated in hearings (Titles omitted and in alphabetical order.)

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Regarding the Independent Nature of These Recommendations

These policy recommendations are based on discussions at meetings HGPI held for this project and have been compiled in HGPI's capacity as an independent health policy think-tank. It does not, in any capacity, represent the opinions of any participating expert, speaker, related party, or organization to which those parties are affiliated.

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