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## Review

# Recent progress and concerns regarding the Japanese immunization program: Addressing the "vaccine gap"



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#### ABSTRACT

Recent progress in the Japanese immunization program has partially closed the "vaccine gap," i.e., the deficiencies in that program relative to immunization programs in other developed countries. During the last several years, seven new vaccines (12 new products, excluding influenza vaccines) have been introduced in Japan. Five of these new vaccines are produced outside Japan and four are now included as routine vaccines in the National Immunization Program, which is a new development in the licensing and financial support of imported vaccines. However, along with this progress, important concerns have arisen regarding the Japanese immunization program. A rubella epidemic among adults, in 2012–2013, resulted in more than 40 cases of congenital rubella syndrome as of March 2014. In addition, the temporary withdrawal of the active governmental recommendation for human papilloma virus vaccines, in 2013–2014, highlighted challenges in the current Japanese immunization system. Furthermore, some important vaccines – including vaccines for hepatitis B virus, mumps, varicella, and rotavirus – are still not included in the National Immunization Program and have been categorized as voluntary vaccines since their introduction. The possibility of their inclusion in the National Immunization Program remains a matter for discussion. We hope that future initiatives will further address the vaccine gap and protect Japanese children from vaccine-preventable diseases.

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## 1. Introduction

Recent progress in the immunization program of Japan has begun to close the "vaccine gap," a term used during the last two decades to refer to the deficiencies of that program relative to programs in other developed countries [1]. Seven new vaccines (12 new products, excluding influenza vaccines) have been introduced in Japan since 2008 (Table 1): a Haemophilus influenzae type b (Hib) vaccine, 7- and 13-valent pneumococcal conjugate

Abbreviations: Hib, Haemophilus influenzae type b; PCV, pneumococcal conjugate vaccines; RV, rotavirus vaccines; HPV, human papillomavirus; wIPV, Salk-derived polio virus vaccine; DTaP-sIPV, diphtheria, tetanus toxoid, acellular pertussis, and inactivated, Sabin-derived polio vaccine; JE, Japanese encephalitis; NIP, National Immunization Program; VPD, vaccine preventable diseases; MR, measles and rubella; BCG, Bacille de Calmette et Guérin; VZV, varicella-zoster virus; NITAG, National Immunization Technical Advisory Group; MMR, measles, mumps, rubella; HBV. hepatitis B virus; WHO. World Health Organization.

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vaccines (PCV7 and PCV13), rotavirus vaccines (monovalent [RV1] and heptavalent [RV5]), human papillomavirus (HPV) vaccines (bivalent [HPV2] and quadrivalent [HPV4]), an inactivated Salkderived polio virus vaccine (wIPV), diphtheria, tetanus toxoid, acellular pertussis, and inactivated Sabin-derived polio vaccines (DTaP-sIPV, 2 products), and inactivated Vero cell-derived Japanese encephalitis vaccines (JE, 2 products). Among them, after licensure, the wIPV, DTaP-sIPV, and JE vaccines were introduced to the National Immunization Program (NIP) as routine immunizations to replace the oral polio vaccine, DTaP, and inactivated mouse brain-derived JE vaccine, respectively. In January 2011, a temporary national budget was created to support the costs of the Hib, PCV7, and HPV vaccines, and they have been included in the NIP since April 2013. Later, PCV7 was uneventfully replaced by PCV13 in November 2013. Five of the seven vaccines (8 of the 12 products) are produced in foreign countries, which is a new development in the licensing and support of imported vaccines in Japan.

Vaccine availability is improving, recognition of vaccinepreventable diseases (VPD) is increasing, and more vaccines are now included in the NIP; however, some concerns remain regarding immunization, which indicates that the current Japanese immunization system needs further improvement. The Japanese rubella

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epidemic in 2012–2013, which mainly affected adults [2], resulted in more than 40 cases of congenital rubella syndrome, as of March 2014. Most of the people who developed rubella were men aged 20-40 years, as this group had not received the rubella vaccine during their youth [3]. Vaccination rates among the susceptible population remain low because catch-up vaccines for targeted individuals are categorized as voluntary and are an out-of-pocket expense. Many local governments offered financial support for vaccines in targeted populations, which increased vaccination rates. However, the shortage of vaccines developed after the demand increased for rubella vaccine and measles and rubella (MR) vaccine. Another important problem is that, due to reports of more than 30 cases of chronic pain syndrome, the government temporarily withdrew its active recommendation for HPV vaccines, beginning in June 2013. Unsurprisingly, immunization rates for HPV vaccines decreased sharply due to fears that the vaccines might cause adverse reactions/events.

In this review, we summarize recent progress and discuss current concerns regarding the Japanese immunization program.

# 2. Recent progress in the Japanese immunization program

# 2.1. Revision of the immunization law

In April 2013, the Japanese Immunization Law underwent major revision. The most important changes were (1) the inclusion of three new vaccines (the Hib, PCV7, and HPV vaccines) in the NIP and continuing discussion of including the remaining important vaccines in the NIP, (2) further government financial support for immunization, (3) changes in the timing of Bacille de Calmette et Guérin (BCG) vaccination, (4) establishment of a new committee for national immunization policy, (5) legislative authorization to launch a vaccine adverse events reporting system, and (6) development of a national immunization policy.

# 2.2. Introduction of new vaccines to the NIP

Vaccine licensing has traditionally been slow in Japan [1], particularly for vaccines manufactured in foreign countries. As compared with the United States, the Hib vaccine was introduced 21 years later (1987 vs. 2008) and the PCV7 vaccine was introduced 10 years later (2000 vs. 2010) in Japan. However, as part of recent progress in vaccine licensing (Table 1), the government allocated a temporary national budget for the Hib, PCV7, and HPV vaccines

in January 2012, and these three vaccines were included in the NIP when the law was revised. After fees were decreased for vaccination recipients, vaccination rates increased and the effectiveness of the vaccines was confirmed in data from selected populations [4]. Analysis of data on Hib infection before (2008–2010) and after (2012) government financial support shows that Hib meningitis and invasive diseases (excluding meningitis) decreased by 92% and 82%, respectively. Data on pneumococcal diseases during the same time periods show that pneumococcal meningitis and invasive diseases (excluding meningitis) decreased by 71% and 52%, respectively. The latest Japanese immunization schedule by the Japan Pediatric Society is shown in Table 2 [5], demonstrating that the schedule is similar to that of other developed countries.

These effectiveness data highlight the importance of vaccine availability and financial support [6], which have led to high vaccination rates and lower incidences of invasive bacterial diseases among children. Additionally, as of September 2014 the government will include the varicella-zoster virus (VZV) vaccine (for children aged 1–5 years, 2 dose schedule) and 23-valent pneumococcal polysaccharide vaccine (for adults aged ≥65 years) in the NIP. The VZV vaccine uses the Oka strain and was developed by Takahashi and colleagues in Japan in the early 1970s [7]. Its inclusion in the NIP was strongly desired by most Japanese pediatricians due to the clinical burden associated with VZV. The inclusion of new vaccines in the NIP is another step in addressing the vaccine gap.

#### 2.3. New national budget for immunization

Previously, the law required that the immunization budget for vaccines be split evenly by the national and local governments. However, inadequate financial support from the national government was a serious problem, as it created a financial burden for local government. The revised law increases support from the national government, from 50% to 90%, thus decreasing the financial burden for local governments. We hope that this trend toward greater national support for immunization continues.

# 2.4. Changes in the timing of BCG vaccination

Japan is one of a few developed countries that vaccinate all children for BCG. The vaccine uses the Tokyo 172 strain and is administered by percutaneous, multi-needle puncture [8]. Universal immunization is considered necessary because the incidence of tuberculous diseases remains high; the incidence of new

**Table 1** Vaccines recently licensed in Japan (excluding influenza vaccine).

Year licensed	Month licensed	Vaccines	Trade name	Foreign (F) or domestic (D)	In NIP (starting month, year)
2008	December	Haemophilus influenzae type b	Act-Hib	F	Yes (April 2013)
2009	June	Vero cell-derived, inactivated Japanese encephalitis	JEVIK V	D	Yes (June 2009)
	December	Divalent human papilloma virus	Cervarix	F	Yes (April 2013)
2010	February	7-Valent conjugate pneumococcal	Prevenar	F	Yes (April 2013)
	April	Vero cell-derived, inactivated Japanese	Encevac	D	Yes (April 2011)
2011	•	encephalitis			` • '
	August	Quadrivalent human papillomavirus	Gardasil	F	Yes (April 2013)
	November	Monovalent rotavirus	Rotarix	F	No
	July	Heptavalent rotavirus	Rotateq	F	No
2012	September	Salk-derived, inactivated polio	Imovax	F	Yes (September 2012)
	November	Diphtheria, tetanus toxoid, acellular	Tetravix,	D	Yes (November
		pertussis, and inactivated, Sabin-derived polio vaccine	Quatrovax		2012)
2013	November	13-Valent conjugate pneumococcal	Prevenar 13	D	Yes (November, 2013)

NIP: National immunization program.

<sup>\*</sup> Active vaccine recommendation is temporally withdrawn from June 2013 as of March 2014.

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