Revision of Preventive Vaccination Law and Future Trends

JMAJ 45(2): 75–79, 2002

Hitoshi KAMIYA

Director, Mie National Hospital

Abstract: In Japan, the drastic reformation implemented in 1994 has transformed the concept of preventive vaccination. This reformation indicated a change in the vaccination system from mass vaccination to individual vaccination and from compulsory (mandatory) vaccination to recommended (effort-requiring) vaccination. At the same time, the importance of promoting understanding of the possibility that vaccination may invite an unexpected health problem was pointed out. Because this revision of the vaccination system was a substantial change, a review of the details of the revised system was scheduled for a date five years later. A review conducted in 1998 pointed out importance of educating students about the role of vaccination, which will lead to a correct understanding of infectious diseases and the role of vaccinations. The importance of the collaboration between the Ministry of Health, Labor and Welfare and the Ministry of Education, Culture, Sports, Science and Technology was also pointed out in the promotion of the preventive vaccination system. Since 1994, the influenza vaccine has been administered on a voluntary basis, which has resulted in a significant decrease in the rate of vaccination among Japanese. Therefore, even susceptible elderly people and those at high risk of influenza frequently forego the vaccination. Thus, the necessity of influenza vaccination was to be reconsidered in the review. The physicians responsible for vaccinations are reimbursed by the medical care system and the promotion of preventive vaccination among the public is expected in the future.

Key words: Preventive vaccination (vaccine); Revision of Preventive Vaccination Law; Review of revised Preventive Vaccination Law; Guidelines for preventive vaccination

Introduction

The prevention of infectious diseases is the ultimate goal of the countermeasures instituted against them. All people, irrespective of age, sex, race, lifestyle, and socioeconomic condi-
tions, are at risk of contracting infectious diseases. Those who contract infectious diseases where appropriate treatment has been established and those who have already received vaccinations are at lesser risk of aggravation of or death from infectious diseases.

The history of the legislation regarding infectious diseases has its roots in the Infectious Disease Prevention Act, which was enacted in 1897. The latest legislation is the “Law for the Prevention of Infectious Diseases” (New Infectious Diseases Prevention Act) which was implemented in 2000. It is aimed at promoting the prevention of infectious diseases in the 21st century. The New Infectious Disease Prevention Act naturally stipulates the details of preventive vaccinations. In this report, the author evaluates the current revisions and predicts the future trends of preventive vaccinations in the 21st century via a discussion of how the countermeasures for infectious diseases are implemented and what countermeasures are to be practically introduced to cope with conditions globally.

Necessity for Vaccination and Current Trends

The pathogens of infectious diseases such as viruses, bacteria, and the toxins produced by bacteria are used to prepare vaccines. Although their toxicity is reduced, vaccines produce immune responses against infectious agents or their toxins; the vaccines are orally administered or inoculated by injection. Methods of administration are defined by the Preventive Vaccination Law to maintain public health. The Preventive Vaccination Law was revised in October 1994.

The main points of this revision are summarized as follows. The infectious diseases covered by the law were reviewed because of changes in the prevalence of infectious diseases. The vaccination practice was changed from compulsory (mandatory) vaccination to recommended (effort-requiring) vaccination. (The penalty for not receiving vaccinations was abolished and the rule covering informed consent was rigorously enforced.) The necessity of establishing an effective and safe vaccination system was emphasized. (The switch from mass vaccination to individual vaccination indicates the change from protection of the group to protection on an individual basis, and the suppression of mass infection is anticipated as a result of the promotion of individual vaccination and increasing the percentage of those with full immunization.) The necessity of developing appropriate countermeasures for rapid relief of injury to health caused by vaccinations (medical treatment and compensation for unexpected adverse reactions) has been defined.

This revision provided for a review to be conducted in five years. The subcommittee on preventive vaccination related affairs was organized under the committee on infections, the council for public health. Since June 1998, a total of 18 meetings were held and the final report was submitted to the committee on July 5, 1999. This report was approved after its partial modification. Although the council for public health submitted the report to the Minister of Health and Welfare, the proposal was discarded as the Diet was dissolved before the initiation of discussion on the report. The proposal was to be resubmitted for discussion to the extraordinary session of the Diet scheduled in September 2000. As the discussion of the proposal requires a series of official procedures, whether or not the preparations for implementation in 2001 will be completed is of a great concern.

Main Points of the Report

1. Basic concept

Parents, physicians and the Government are all called upon to recognize that “prevention is superior to treatment,” and to understand the natural course of the infectious diseases for which vaccines are prepared. In Japan, students have few opportunities to study health educa-
tion at school and their knowledge of diseases is extremely limited. Therefore, they seem to lack the basic understanding of the necessity of receiving preventive vaccinations. In the revision, the introduction of health education covering the importance of vaccinations into the school curriculum is expected to be discussed.

2. Types and timing of routine vaccinations

The discussions in the following sections are based on the official guidelines published by the Ministry of Health and Welfare in 1994.

1) Routine vaccinations and voluntary vaccinations

There are seven routine vaccinations for poliomyelitis, diphtheria, pertussis, tetanus (diphtheria-pertussis-tetanus: DPT), measles, rubella, and Japanese encephalitis. In addition to these vaccines, BCG is administered according to the Tuberculosis Control Law. All eight vaccinations are indispensable for maintaining good health, and epidemic conditions have been surveyed according to the New Infectious Disease Prevention Act.

In 1994, the Preventive Vaccination Law was revised and appropriate agents for routine vaccinations were selected with due consideration for their potency in controlling the epidemics of specific infectious diseases, their prophylactic effects on those at high risk of severe complications from primary disease and their role as a measure to protect individuals from certain aspects of society.

Based on these basic principles, mass vaccination against influenza, which has rarely produced a consistent immune response and controlled epidemics, was excluded from routine vaccinations for elementary school and junior high school students. Since the revision, influenza vaccinations are administered on a voluntary basis and indicated only for the adults aged 65 years and older, patients with bronchial asthma and/or heart disease and individuals at high risk of immunodeficiency from primary diseases or drug administration. At the time of the discussion, other vaccinations such as vari- cella, mumps and Haemophilus influenza were included. After the exclusion of the influenza vaccination from routine vaccinations, people have less awareness of the seriousness of influenza as well as vaccination. This lack of awareness of the necessity of individual prophylaxis and the prevention of development and aggravation among the public has been pointed out.

Due to the recent increase in mass influenza infection and mortality from influenza during the winter among the elderly living in nursing homes, in addition to the increase in child morbidity from encephalitis and encephalopathy during a period of widespread influenza, experts point out the relationship between influenza and these phenomena. In the recent review of the vaccination system, the routine administration of influenza vaccination to adults aged 65 years and older was proposed together with its adoption under the Preventive Vaccination Law. During the discussion, it became clear that a categorization of preventive vaccination should be implemented in the revision of the law, because while the influenza vaccination was administered to adults with the diseases and was effective to prevent the development of influenza on individual basis, it was not done to control the epidemics of the virus. Under the proposed categorization, the specified infectious diseases were divided into two groups: the seven infectious diseases were in group 1, and influenza was in group 2.

While vaccination for infectious diseases in group 1 are strongly recommended, this is not the case for group 2. Therefore the relief of injury to health by vaccination differs depending on this classification of infectious diseases. Individuals are to be compensated for adverse reactions attributable to vaccine at the level which is similar to that defined by the Law of the Organization for Drug ADR Relief, R&D Promotion and Product Review. The proposed system, which defines the compensation for victims under Preventive Vaccination Law, appears to have been welcomed by the physicians responsible for vaccinations.
Regarding infant influenza, the implementation of a survey on the effectiveness of influenza vaccination sponsored by the Ministry of Health and Welfare has been recommended and the necessity of discussing appropriate countermeasures based on the results obtained from the survey was pointed out.

(2) **Timing of routine vaccinations**

Although special consideration is given to routine vaccinations so that they may be completed within 90 months after birth, the heads of cities, wards, towns, and villages responsible for vaccinations often shorten the periods of routine vaccinations because of specific local conditions. The revision of the vaccination system stated that while individuals who require vaccination are advised to receive them within a standard period determined according to the epidemic conditions of infectious diseases and it stated that patients who fail to receive them during the standard period can still receive them within the period specified by the Preventive Vaccination Law.

The establishment of one or two preventive vaccination centers per prefecture has been proposed and, as of this year, several centers have started to provide various services including vaccinations and counseling. These preventive vaccination centers can be used by children with underlying diseases who are unable to receive vaccinations at general clinics, foreigners and those returning to Japan or living overseas who are unable to receive vaccinations at general clinics. The final goal of the establishment of these centers are to enable all individuals to receive the necessary vaccinations under the same conditions as to the standards established in their residential prefectures. While the number of those who visit these centers outside their residential prefectures are few, (cases such as babies born in the prefectures of their maternal grandparents, individuals returning to their hometowns, businessmen on temporary postings outside his or her original residents), the idea of this simple but important service was added to the proposal.

3. **Preventive vaccination notebook**

The completion of vaccinations is currently recorded in the mother-and-baby notebook. In view of the current changes in society including the increase in the number of individuals undergoing vaccinations in foreign countries and the need to respect the privacy of divorced couples and their children, the preparation of preventive vaccination records, not as a record of mother and child but as a life-long individual record of vaccination, has been proposed.

4. **Rate of preventive vaccination**

Since the introduction of the individual vaccination system, the decrease in the rates of preventive vaccinations among older elementary school pupils and junior high school students, probably caused by the fact that they are now required to visit the clinics with their parents, has become a serious problem. In the case of junior high school students, the system will soon be modified. In addition, because the age range of individuals to be vaccinated has been widened since the revision, the calculation of a precise vaccination rate is becoming difficult. In view of the differences in vaccination rates created by the multiple calculation methods, the rates should be calculated according to the data obtained from routine physical examinations for infants at one and a half years and three years and the physical examination conducted at the time of entering elementary school. In this way, more consistent vaccination rates can be obtained. In cooperation with the Ministry of Health and Welfare, the heads of prefectures, cities, towns, and villages are to establish a simpler calculation method through discussion.

5. **The guidelines for preventive vaccination**

The first official preventive vaccination guidelines issued by the Ministry of Health and Welfare came at the time of the revision of the law in 1994. These guidelines provide the basic infor-
mation on vaccinations required by all physicians responsible for vaccinations, such as the standard for vaccinations and the appropriate treatment for adverse reactions caused by vaccinations. While the guidelines aimed to clarify some of the complicated issues in the law by referring to specific cases, some of the explanations have occasionally caused misinterpretations and confusion. Such problems may have occurred due to the limited number of pages and to the fact that it was the very first set of guidelines to be printed. Thus, the guidelines are expected to overcome these issues after the latest review and will be improved.

A more comprehensive vaccination system will therefore be established in the near future. The guidelines issued by the Ministry of Health and Welfare are regarded as the official guidelines for vaccinations although there are several personal handbooks available.

6. Future trends

In order to reduce the number of vaccinations and increase the vaccination rates, various types of multiple mixed vaccines are to be developed in the future. Pediatricians have been responsible for vaccinations. However, since vaccination rates among adults are expected to increase in the future, physicians are encouraged to become involved in administering vaccinations.

The immunizing agents indicated for adults are vaccines for tetanus, hepatitis B, hepatitis A, measles, varicella, and mumps. The latter three vaccines are indicated only for adults with no previous history of the diseases. It is necessary to implement a campaign to promote vaccination in collaboration with the Japan Medical Association.

Conclusion

In the present study, I have discussed the important aspects of the proposal, together with present conditions and future trends. This report also includes provisions which protect the physicians responsible for vaccinations. Furthermore, the comments from those involved parties throughout the country have been reflected in the proposal. The author hopes that the procedures for the official revision will soon be completed and that an effective system based on the proposal will be practically introduced. The author is keen to follow the future trends in the vaccination system.

REFERENCES