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Considering economic analyses in the revision of the preventive vaccination law: A new direction for health policy-making in Japan?

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ABSTRACT

Evidence of a significant vaccine policy shift can be witnessed not only in the number of new vaccines available in Japan but also in the way that vaccine policy is being formulated. In 2010, policy makers decided for the first time ever to commission economic analyses as a reference in their consideration of subsidy allocation. This research offers a firsthand account of the recent changes in vaccine policies by examining the decision-making process from the perspective of the researchers commissioned to perform the economic evaluations. In order to understand the vaccine policy-making process, a review was made of all the documents that were distributed and discussed during the government committee meetings from February 2010 when the revision of the Preventive Vaccination Law was initially proposed to May 2012 when the final recommendations were made. Economic evaluations were conducted for seven vaccines under consideration in the routine immunization program (*Haemophilus influenzae* type b or Hib, pneumococcal disease for children and adults, human papillomavirus, varicella, mumps, and hepatitis B). All were cost-effective options, except the Hib and hepatitis B vaccines. Nonetheless, all the vaccines were recommended equally for inclusion in the routine immunization program. While it is significant that policy-makers decided to commission economic assessments at all, various issues remain regarding the influence of external pressure, the choice of evaluation methods and the implications of using cost-effectiveness analyses on the future of Japanese health policy-making.

1. Introduction

In March 2013, a Cabinet decision was made to revise the Preventive Vaccine Law (PVL), the foundation for all of Japan's vaccine policy, first introduced in 1948 by the US Occupation authorities [1]. The revision included a provision to make three vaccines routine: *Haemophilus influenzae* type b (Hib), human papillomavirus vaccine (HPV), and pneumococcal conjugate vaccine (PCV) for

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children [2]. The decision to revise PVL came in response to the final recommendations made by the Infectious Disease Sectional Committee of the Tuberculosis and Infectious Diseases Control Division of the Health Service Bureau of Ministry of Health, Labour and Welfare (MHLW) where discussions took place from February 2010 to May 2012 (an organizational chart is available on the MHLW website [3]).

To critics of the current vaccine policies, the decision is seen as a significant improvement since Japan is often perceived as an "backward nation" in terms of vaccine availability, and only a limited number are widely used [4]. While at least one new vaccine approval was made every year in the United States from 1991 to 2006, only two new vaccines, the hepatitis A (1995) and a modified version of MMR, the measles–rubella vaccine (2005), received approval in Japan over the same period [5–8]. Since 2007, however, Japanese regulators have already approved four new vaccines: Hib (January 2007), HPV (October 2009), PCV for children (October 2009), and rotavirus (October 2011) [9]. The three vaccines (HPV, Hib, and PCV) were selected as candidates for routine immunization based on the fact that a financial scheme to provide special subsidies had already been in place since October 2010 [4].

To better understand why vaccination has recently come to the fore as major focus of health policy-making, we should first consider how vaccines are procured and administered in Japan. According to current policy, local governments receive annual allocations from the central government for the purpose of providing various healthcare services, one being routine immunizations [10,11]. Consequently, it is the responsibility of the local governments to purchase and administer the eight *routine* vaccines: diphtheria, pertussis, tetanus, polio, measles, rubella, BCG, J. encephalitis, and influenza (for persons 65 years of age or older), to their residents, who can receive them, if they so choose, at no or a negligible cost. Regarding *voluntary* vaccines: Hib, PCV (for children and adults), HPV, varicella, mumps, hepatitis A and B and rotavirus, however, the full cost must be borne by the recipient [12]. While routine vaccination was once mandatory in Japan, since the 1994 revision of PVL, citizens are, according to the wording of the Law, "obliged to make efforts to vaccinate," though vaccination itself is no longer mandatory [10,13].

Following the approvals of HPV, Hib, and PCV as voluntary vaccines, only a small number of local governments had sufficient financial resources to offer their residents the opportunity of receiving them due to their relatively high cost [14–16], and this led to disparities in vaccine access in a country where healthcare coverage is universal and patients are more sensitive than those in other countries to healthcare inequalities [17]. In order to eliminate inequalities in access to important vaccines while also promoting prevention as one of the best uses of scarce financial resources, MHLW initiated a discussion of the existing vaccine policies [13,18]. To make a fair evaluation of whether or not the government should allocate public funds nationwide to cover non-routine vaccinations, regulators decided to employ a wide range of policy-making tools, one being economic evaluations.

According to OECD Health at a Glance 2013, Japan's health expenditures total 9.6% of gross domestic product. While the level is lower than in most OECD countries, it is accelerating at a faster rate [19] due to a rapidly aging population and increased use of advanced medical technologies [20]. One solution that the report offered to Japanese policy-makers was to look for ways to create greater value for the money spent on health. Many developed countries have already done so by adapting health technology assessment (HTA), which considers both costs and benefits simultaneously as a tool to allocate health resources efficiently and equitably in health policy decision-making. However, Japan still lacks such an evidence-based system that prioritizes economic analyses in determining official pricing and reimbursement of new pharmaceuticals and medical devises in its healthcare system.

On the other hand, as this paper will demonstrate, there are signs of a significant change. Indeed, in 2011, MHLW officials commissioned working groups to conduct economic evaluations including cost-effectiveness analyses; moreover they considered various vaccine policy options in their decision-making process based on those findings. The purpose of this article, written in part by the participants of the MHLW working groups will be to provide a firsthand account describing the most recent vaccine policy-making process in Japan using two cases studies, the Hib and hepatitis B vaccines, as well as to consider what implications the use of economic evidence will have on the future direction of healthcare policy formulation.

2. Vaccine policy revision process

The policy-making process officially got underway in December 2009 with the first meeting of the Infectious Disease Sectional Committee. The process leading to the government's decision to commission economic evaluations, however, began later in August 2010 with the appointment of eight working groups comprised of infectious disease specialists, clinicians, epidemiologists and health economists to conduct assessments of the two routine (pertussis and polio) and seven voluntary vaccines (Hib, PCV for children and adults, HPV, varicella, mumps, and hepatitis B). The data gathered by the working groups was then compiled into factsheets mainly by researchers at the National Institute of Infection Disease (NIID) and used as a reference over a two-year period at regular meetings attended by MHLW regulators, independent experts, representatives from a broad spectrum of special interests such as the physicians' lobby and pro- and anti-vaccination organizations, local government officials, journalists, etc. The roles of committee meetings and the purpose of the discussions are summarized in Fig. 1.

After regulators compiled the data that they had commissioned from the eight working groups, including the economic evaluations, a series of Scientific Deliberation Council meetings got underway. Since the passage of the "Act on Access to Information held by Administrative Organs," all administrative documents distributed at governmental meetings including the minutes must be made available to the public, and all the relevant data can be downloaded for a period of five years from the MHLW website [21]. In order to accurately summarize the vaccine