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助産師への乳児期予防接種に関する教育介入の効果

Effectiveness of an Educational Intervention for Midwives  
about Early-Childhood Immunization

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## Background

As one of the most cost-effective measures for infectious disease control, immunizations have played a prominent role across the world (WHO/EURO, 2014). Compared to the 1950s, the era of ‘not introducing vaccines to Japan’, the number of deaths due to vaccine preventable diseases (VPDs) dropped dramatically over the past sixty years (see Table 1). The World Health Organization (WHO) advocates that, “every child has the right to live free from VPDs in the 21<sup>st</sup> century” (WHO/EURO, 2014).

**Table 1. Death toll of VPDs before and after introduction of vaccines into Japan**

VPDs	1950s number of patients	1950s number of deaths	2010 number of deaths
Pertussis	50,000~150,000	10,000~17,000	10
Diphtheria	10,000 ~50,000	2,000 ~3,800	0
Tetanus	2,000	2,000	10~15
Poliomyelitis	2,000 ~5,600	100s ~1,000	0
Measles	200,000	1,000s~20,000	< 10
Japanese encephalitis	1,000 ~5,000	2,000	0~2

From: Nakayama T (2011) Clinic All-Round.Vol.60, No.11, 2173-5, modified by researcher

Immunization has an aspect of social defence (what is termed “herd immunity”), which protects not only the vaccinated individual from the target disease but also brings the immune effect to the social group he or she belongs. As a rule, 85~95% of vaccination coverage is required to prevent an epidemic of VPDs in a social group (Plotkin, Orenstein, & Offit, 2012). Therefore, various efforts to increase immunization uptake have been deployed worldwide.

The United States, along with other developed countries, have introduced a large number of vaccines and the childhood immunization coverage is kept high (Australian Government, Department of Health, 2013; CDC, 2014; Health & Social Care Information Centre, 2013). Sufficient coverage can be accounted for by the system that recommended vaccines are basically provided as routine vaccination without personal expense. The completion of these vaccines is often a type of prerequisite to enrol in group education. While exemptions can be granted based on state statute, immunization is implemented on an opt-out basis in these countries.

On the other hand, Japan’s immunization system does not count all recommended vaccines as routine vaccine. The recommended vaccines are categorized into two groups: routine vaccines and

voluntary vaccines. The routine vaccines are regulated by Japanese immunization law and administrated without out-of-pocket outlay, but the voluntary vaccines are not under the law and paid for by private resources. Since both groups of vaccines are not duty to immunize but “effort duty” without mandatory power, the decision of childhood vaccination is dependent on parental choice (Saitoh & Okabe, 2012). Compared to routine vaccines, the un-routinized vaccines are considered less important (Saitoh & Okabe, 2012) and this leads to the low coverage for the voluntary vaccines (Sadzot-Delvaux et al., 2008).

The term “vaccine gap” has been used for past twenty years, which indicates that Japan’s immunization program has fallen behind other developed nations (Saitoh & Okabe, 2012). However, the gap has been filled up in recent years by introducing a number of newly approved vaccines. Along with that progress, the immunization law was also revised in 2013. As a result, infants are expected to follow a busy schedule of vaccination, particularly in the first six months of life. Accordingly, new parents are required to collect information and make decisions about their child’s immunization during the early postnatal period. The rapid and frequent changes in the national program also has posed a challenge to service providers. Health facilities and local administration offices where the immunization program is implemented are too preoccupied to response to the changes, consequently the provision of parental support is left to individual efforts. The lack of support systems with particular reference to the delivery of unified information to parents at appropriate times creates an increased risk of missed opportunity for childhood vaccination.

Few studies are available on the factors influencing parental decision-making for early childhood immunization and on immunization uptake during the recent transition period. In order to determine an effective intervention for the present study, the researcher conducted a questionnaire survey as a preliminary study targeted at mothers who had infants aged 6 months to less than one year (Endo, 2014). The results showed that the lack of information and knowledge was the main obstacle for parents to immunize all recommended vaccines for their children. The majority of respondents answered the reason to omit some vaccines (mostly voluntary vaccines of hepatitis B [HB] and rotavirus infections) was simply that they did not perceive the need for these vaccines. A concern about the adverse events of vaccines or a belief in anti-immunization was not the main reason for avoiding immunization for the most of the respondents. Moreover, the mothers who started information correction early, had multiple information sources, and possessed the knowledge about vaccines, were

more likely to allow immunization from large variety of vaccines for their children. The majority of respondents indicated health facilities were their leading information source and health care providers (mostly paediatrician or physician) were their main advisor. Therefore, the quality of support and the attitude of health personnel were thought to be the key factors for the immunization uptake. On the other hand, a small number of respondents recognized nursing personnel (nurse, midwife and public health nurse) as their main advisor, thus efforts need to be made for these health care providers to have a more active role as an information provider.

Effective information provision to parents from the earliest stage possible requires all health care providers involved with the couples during pre and post-natal period to bear a part in promoting immunizations. Responding to the recent 2012-2013 rubella epidemic in Japan (Ujiie, Nabae, & Shobayashi, 2014), the importance of raising awareness of immunization for the reproductive age group has been increasing. Among various health care providers involved in maternal and child health, the present study focuses on the role of midwives in promoting immunization. Midwives are the profession who have regular contact with expecting couples from the earliest stage. As the Health Protection Agency in the U.K (2011) notes, “midwives are well placed to make a significant impact on public health by promoting vaccine uptake during the course of their work” (p.10).

Nevertheless, the interview with in-service midwives conducted by the researcher found that the midwives feel challenged to provide immunization related information to their clients. The interviewees expressed their feelings as, “I hesitate to inform them about vaccinations because I do not think I have enough knowledge about it”, “I am not confident of providing the up-dated information as the program has changed a lot”, and “only limited time can be spent for immunization guidance as we have to cover various other topics”. While the midwives mentioned some organizational barriers, their main concerns for promoting immunization were about the lack of information and knowledge of immunization.

Since a standardized training system in immunization for nursing personal remains to be established in Japan, midwives have limited opportunities for in-service training on immunization unless engaged directly in pediatric service. As a result, catching-up on the latest information as well as developing the skills for effectively communicating with parents relies on midwives’ individual efforts. In fact, the promotional activities of immunization are not included in the competencies for midwifery practice stipulated by the Japanese Midwives Association (2010). On the contrary,



midwives are considered as the front line care providers in public health service including immunization in other developed nations (American College of Nurse Midwives, 2014; Australian Nursing & Midwifery Federation, 2014; Public Health England and Department of Health, 2013). The midwives' work covers not just perinatal period but now has extended to the long period of life cycle such as childhood, adolescence, and menopause (ICM, 2011). Japanese midwives are able to make a further contribution to long-term health of the society by providing information and advice on immunization for the clients and their families.

In order to improve the capacity of midwives for promoting immunization, the present study developed an immunization educational program specifically for midwives and examined the effectiveness of the program by a comparison between intervention and control groups.

### **Purpose**

The purpose of this study was to develop an educational program aimed at improving midwives' knowledge for promoting immunization and to examine its effectiveness by a controlled before and after trial.

### **Significance of study**

Through improving midwives' capacity for promoting immunization, women and their families can be provided the necessary information and advice at an early stage in the perinatal period. Providing the support for parents ahead of time should promote the uptake of scheduled initial vaccination.

Additionally, the developed and examined educational program in the present study will provide a basis for the future development of an immunization in-service training for midwives.

**Definition of term**

Immunization-promoting activities by midwives: these activities include providing information and advice on the vaccines targeted for women, infants and their family members. The assessment of immunization status to determine the need for vaccination, the scheduling and rescheduling of vaccination based on individual needs is also included in the associated task. The administration, storage and handling of vaccines are not included since the present study assumes only the activities implemented by midwives engaged in obstetric service.

## **Literature Review**

### **Immunization programs around the world including Japan**

In order to enhance vaccine availability throughout the world, in 1974 WHO launched an Expanded Program on Immunization (EPI). Initially, EPI had provided basic original vaccines for six targeted VPDs (DPT [diphtheria, pertussis, tetanus], poliomyelitis, measles, and BCG [tuberculosis]) for developing countries. In the 2000s WHO (2014a) extended the number of basic vaccines to eight by adding HB and hemophilus influenza type B (Hib) vaccines. As a part of EPI, the vaccination of monovalent tetanus toxoid for pregnant women has also been widely implemented in developing nations. Along with EPI, a notable global effort to promote the provision of vaccines for developing countries is the Global Alliance for Vaccines and Immunization (GAVI alliance) established in 2000. The alliance was jointly organized by public and private sectors in both developed and developing nations and has created a unique funding mechanism as well as its own vaccine procurement and supply system. More than 70 developing countries have received assistance from GAVI alliance since its inauguration (GAVI, 2014).

While WHO defines the recommended vaccines on a regional or population basis, ten selected vaccines (BCG, HB, poliomyelitis, DPT, Hib, PCV [Pneumococcal Conjugate Vaccine], rotavirus infections, measles, rubella, HPV [Human Papilloma Virus]) are recommended for all in every nation as routine vaccination (WHO, 2014b). A country-specific immunization program in developed countries is usually determined by reference to the EPI basic vaccines and the WHO recommendation with consideration for the situation in each country such as the prevalence of VPDs, the capacity of vaccine production, and the budgetary allocation. Therefore, each developed country has a different immunization program in terms of the variety of routine vaccines, the timing of vaccination, and the number of booster vaccination.

Currently, twenty-one VPDs exist in the world, of which the vaccines against the 17 diseases (13 vaccines) are available as childhood immunization by age six in Japan (six vaccines are administered for infants under the age of one). As of May 2015, the eight out of 13 vaccines are administered as routine vaccination in Japan, but the rest of vaccines are voluntary vaccines are an out-of-pocket expense. The coverage of the voluntary vaccines is generally lower than the routine vaccines, due to the cost burden and the lack of awareness of their needs (Endo, 2014; Ono & Numazaki, 2010;

Tsuda, Kosaka, Takayanagi, Kono, & Watanabe, 2012). In other words, although Japan has introduced newly available vaccines, not all children at the target age are benefited from these vaccines.

On the other hand, in the United States, the country known as effectively running the national immunization program (Kamiya, 2011), all children are recommended to be given the vaccines against 15 VPDs by age six without out-of-pocket expense (Table 2). As a part of efforts to increase the immunization coverage, the number of visits and injections are minimized by practicing simultaneous administration and introducing various combined-vaccines (Kamiya, 2011).

**Table 2. Routine vaccines by age six with comparison of the United States vs. Japan**

<b>Routine vaccines in U.S.</b>	<b>Japan*</b>
Hepatitis B	Voluntary
Rotavirus infections	Voluntary
Diphtheria	Routine
Pertussis	Routine
Tetanus	Routine
Hib (haemophilus Influenzae type b)	Routine
PCV (pneumococcal conjugate)	Routine
Poliomyelitis	Routine
Rubella	Routine
Measles	Routine
Influenza	Routine
Varicella	Routine
Mumps	Voluntary
Hepatitis A	Voluntary
Meningococcal	Voluntary

\* BCG and Japanese encephalitis vaccines are included as routine immunization in Japan

The Advisory Committee on Immunization Practice (ACIP) in the United States developed the national immunization policy of recommendations for the use of vaccines (Smith, 2010). ACIP is an independent body from the government consisting of medical and public health experts and its transparent decision-making process is able to build the public trust on immunization policy. Prior to the regular committee meeting of three times a year, each workgroup formed by the individual agenda prepares a recommendation draft by collecting and analysing all related information. The recommended practice is brought up at the committee meeting for public discussion and for final voting. Anyone can attend and speaks at the meeting, but only the fifteen committee members including one consumer representative have a vote. The voting is orally carried and the discussion in

the meeting is publicized on the Internet (Iwata, 2009). Since the various practical efforts and open administration system lead to the high vaccination coverage in general public, the United States has achieved almost 100% of reduction of nine VPDs (American Academy of Paediatrics, 2012).

The establishment of the Japan's equivalent of an ACIP is anticipated among Japanese experts (Iwata, 2009). In 2010, fourteen academic associations including the Japan Paediatric Society organized a promotion council and made several recommendations to the Ministry of Health, Labour and Welfare. In 2013 in response to these requests, the Ministry upgraded the Vaccine Subcommittee of the Health Sciences Council to the committee (the Immunization and Vaccination Committee of the Health Science Council) along with the revision of the immunization law (Saitoh & Okabe, 2014). Nevertheless, the Ministry of Health, Labour and Welfare established the committee as a consultative but not a policymaking body. The extent to which the committee can ensure its influence, independence, and transparency might be debatable (Nakayama, 2012; Takahata, 2012).

### **Strategies for increasing immunization coverage**

As WHO/EURO (2014) claims, immunization can be one of the most cost-effective measures against infectious diseases provided that high vaccination coverage is ensured. Immunization rate, in other words, the timeliness of vaccination on recommended vaccines is the key indicator of immunization programs. Thus, numerous research articles to assess the effectiveness of the promotional activities are published. Among developed nations, the United States has conducted the largest number of intervention studies including Randomized Controlled Trials (RCTs). Several studies originated from other countries, such as U.K., Ireland and Australia. Since childhood immunization is implemented based on the premise of a mandate, the target population for promoting vaccinations in these nations focuses on the children considered at risk for missed opportunities such as children in poverty, ethnic minorities, or those born prematurely (Abbott, Menzies, Davison, Moore, & Wang, 2013; Johnson, Howell, & Molloy, 1993; Vora, Verber, Pottes, Dozier, & Daum, 2009)

The interventions implemented in those studies are broadly categorized as client (or family)-based or provider-based. The client-based interventions include reminder/recall with telephone and/or mail, home visiting, educational programs and incentive schemes for parents (Briss et al., 2000; Williams, Woodward, Majeed, & Saxena, 2011). The provider-based interventions have provider

reminder/recall by manual searching of client charts or by computerized notifications, provider education, and feedback including incentive scheme (Briss et al., 2000; Williams et al., 2011). Most of the studies consisted of any one of those approaches or multiple combinations. The largest number of studies examined the intervention of client reminder/recall (Briss et al., 2000; Williams et al., 2011). The aim of client reminder/recall in the majority of studies was for promoting booster shots to up date immunization status rather than for initial vaccinations (Jacobson, & Szilagyi, 2005). While Japanese parents are facing the decision on the initial vaccination of their infants, the intervention of reminder/recall in other developed nations intends to encourage the completion of vaccination.

According to a systematic review that included 46 intervention studies (Williams et al., 2011), the parental reminder approach showed a median point change of 11% increase in the immunization uptake among 34% of included intervention groups. For provider-based interventions, provider reminder and provider education reported a median change in the rates of 7% and 8% increase, respectively. The most effective approach to promote immunization rates in this review was feedback programs including provider incentive, which rose a median point in the coverage of 19%.

Provider education intervention, the strategy examined in the present study, is still inconclusive with the mixture of both effective and ineffective results. While a considerable number of studies have been conducted, the positive effect of provider education for immunization uptake is suggested mostly by cross-sectional or before-after studies (Petousis-Harris, Goodyear-Smith, Turner, & Soe, 2005; Uskun E, Uskun S.B, Uysalgenc, &Yagiz, 2008). A few controlled studies aimed at increasing occupational vaccinations of influenza or HB vaccines showed the effectiveness of educational intervention for health care workers (Abramson, Avni, Levi, & Miskin, 2010; Clancy, Cebul, & Williams, 1988). However, no intergroup trial has demonstrated the information delivery effect of provider education in childhood immunization. As a systematic review by Briss, et al (2000) indicates, provider education is part of effective multicomponent interventions, yet provider education-only intervention shows insufficient evidence due to “(1) the small numbers of available studies, (2) limitations in their study design and conduct, and (3) small effect sizes” (p117).

On the other hand, the effect of health care providers' attitudes toward vaccines on immunization uptake is emphasized in several studies. A systematic review with 15 studies (14 cross-sectional studies and one case-control study) (Herzog, et al., 2013) identifies that health care providers' knowledge, beliefs and attitudes about vaccines were positively associated with their intentions to

vaccinate their clients. The review indicated that the provider-based interventions aimed at “increasing knowledge on immunization”, “building beliefs based on scientific evidence” and “developing positive attitudes towards immunization” are likely to lead to increased immunization rates (p.15). As the Summit of Independent European Vaccination Experts (SIEVE) points out, health care providers are the primary information source for the most of parents and their attitudes and views on vaccine safety are the determining factors for the parental acceptance of vaccination (Schmitt et al., 2007).

As for Japanese research articles, most of them were cross-sectional study assessing local immunization coverage or exploring parents’ perceptions about immunization. A few before-after studies conducted by hospitals or local health administration offices were available. The interventions implemented in these before-after studies were face-to-face consultation with a personalized vaccination calendar, parental reminder with mobile phone, and the expansion of opportunity to vaccinate (Akahoshi, Kai, Sakurai, & Kusama, 2005; Inoue, Tamaoki, Sato, Noboru, & Takahashi, 2002; Nerome et al., 2006). Only one RCT of parental education intervention was found originating from Japan (Saitoh et al., 2013). The study examined the effectiveness of a ten-minute session during perinatal period. It compared three-arms (a. received the session during third trimester or b. early postnatal period, and c. control group with no session). The results indicate that the educational intervention for women during pre and postnatal period was effective in increasing early childhood vaccination coverage and maternal knowledge at immunization at three months after delivery (Saitoh, et al. 2013).

## **Parental decision support for immunization**

The major strategies for increasing immunization uptake in developed nations were illustrated by the aforementioned preceding studies. Nevertheless, the reason for children being unvaccinated is not limited to inadvertent missed opportunity but could be a parental decision based on their personal belief. Particularly, the newly introduced vaccines or the vaccines with extensive media coverage of adverse events are thought to increase parents' difficulty in making a personal choice. Considering that immunization-promoting activities may contain an aspect of decision-making support, this researcher reviewed the studies focused on decision support intervention for immunization (Endo & Horiuchi, 2013).

Recently, providing clinical support for patients facing difficult health decisions using Patient Decision Aids (hereafter PtDA) is widely implemented in Western countries (Stacey, et al., 2014). The term 'decision support intervention' in the majority of the searched studies was used in referring to PtDAs. International Patient Decision Aid Standards (IPDAS) collaboration (2012) defined PtDAs as, "evidence-based tools designed to help patients to participate in making specific and deliberated choices among healthcare options" (What are patient decision aids?, para.1). The tools can be various forms as leaflet, DVD, or web-site. PtDAs are usually consisted of several segments including information provision part and personal value clarification part in order to support patient's decision-making process in a stepwise manner. Currently, a couple of PtDAs specialized in HPV vaccine and MMR (measles-mumps-rubella) combined vaccine are available on a web-site (Ottawa Hospital Research Institute, 2014).

In addition to that, several intervention studies have attempted to examine the effectiveness of specialized PtDAs for immunization. Wroe, Turner, and Owens (2005) evaluated a booklet on six early-childhood vaccines targeted at pregnant women, Jackson, et al. (2011) conducted a combined intervention of leaflet and parent meeting on MMR vaccine, and Shourie, et al. (2013) introduced a web-based PtDA on MMR vaccine. A few studies focused on other than childhood immunization, such as a clinical trial of an individual consultation on HB vaccine for physicians (Clancy, et al., 1988) and of a web-based PtDA on seasonal influenza vaccine for health care workers (Chambers, et al., 2012). The study outcomes of these interventions included immunization uptake (or intention to immunize) and one or more indicators for decision support process such as client's knowledge, conflict, anxiety, satisfaction, and confidence. PtDAs aim at improving the quality of decision but do not lead users to



choose one option over another (Ottawa Hospital Research Institute, 2012). Therefore, immunization uptake was not the primary outcome but was placed as the secondary outcome in the most of the studies. Three out of five above mentioned intervention studies showed that the PtDAs were effective for increasing the coverage (Clancy, et al., 1988; Shourie et al., 2013; Wroe, et al., 2005).

### **Role of midwives in promoting immunization**

The role of midwives in promoting immunization varies between Japan and other developed nations. Midwives are inevitably one of the main immunizers in developing countries with a shortage of health personnel, but many developed countries also require midwives to take an active role in immunization practice.

American College of Nurse-Midwives (ACNM) (2013) clearly states in the position paper that the midwives should encourage vaccinations for the clients and their families in order to enhance the people's health of the U.S and of the world. ACNM (2014) outlines the tasks of the midwives in promoting immunization as 1) assessing immunization status of all pre and postpartum women and recommend necessary immunizations, 2) providing latest information about VPDs, the risks and benefits of immunization, and the current immunization guidelines, 3) offering immunization in the clinical setting or referral to the available place to immunize, 4) updating evidence-based knowledge of immunization. The Royal College of Midwives in the U.K (RCM) (2001) also includes information and advice on immunization in one of the roles of the midwives in public health. RCM (2001) emphasises the importance of midwives' contribution to public health for long-term wellbeing of women, children and their families by fulfilling the role. As table three shows, the Health Protection Agency in the U.K (2011) clarifies the role midwives should play in promoting immunization uptake.

The national minimum standards for immunization training in the U.K (the Health Protection Agency, 2005) define the essential requirements of the immunization practitioners who immunize or advice on immunization. According to the standards, the immunization practitioners should be a registered health professional such as nurse, midwife, or medical doctor. The practitioners are required to receive at least a two-day basic training for obtaining the 12 core areas of knowledge on immunization and subsequent annual training for updating the information (Table 4). Other developed countries such as Australia, New Zealand, and the U.S also provide specialized training courses for the health care providers involved in immunization services. Some of the programs are webcasted and

various topic-by-topic learning materials can be obtained through the Internet to support in-service training in these countries.

**Table 3. The role of the midwives in increasing immunization uptake**

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<b>Assessment of immunization status</b>
<ul style="list-style-type: none"> <li>• Make an assessment of the vaccination status of the woman or child</li> <li>• Determine which vaccines can be offered</li> </ul>
<b>Immunization or referral to immunization services</b>
<ul style="list-style-type: none"> <li>• Offer opportunistic or scheduled immunizations in the clinical setting when feasible</li> <li>• Refer the woman and child to the place for immunization when indicated</li> <li>• Assist the family to access immunization services</li> </ul>
<b>Effective communication for overcoming any concerns about vaccines</b>
<ul style="list-style-type: none"> <li>• Promote and advise patients and parents at every available opportunities to overcome any concerns or attitudinal barriers to immunize</li> </ul>
<b>Information collection to assess the woman's susceptibility to VPDs (particularly during antenatal contacts)</b>
<ul style="list-style-type: none"> <li>• Past medical history (particularly varicella, measles, rubella, tuberculosis, HB )</li> <li>• Any infectious diseases the woman may have been exposed and her general health</li> <li>• Immunization history and identify the required vaccines</li> </ul>
<b>Protection of patients by:</b>
<ul style="list-style-type: none"> <li>• Ensuring that the woman is up to date with immunization herself</li> <li>• Providing advice on prevention of infectious diseases</li> <li>• Offering immunization or information on the available place to immunize, and assist to reach immunization services</li> <li>• Providing treatment (e.g. post-exposure immunoglobulin)</li> </ul>
<b>Prevention of infection by:</b>
<ul style="list-style-type: none"> <li>• Before, during and after pregnancy <ul style="list-style-type: none"> <li>Take all necessary measures to prevent infection in the woman</li> </ul> </li> <li>• Encourage breastfeeding <ul style="list-style-type: none"> <li>Confer additional immune protection with IgA to the infant</li> </ul> </li> <li>• Determine the need for vaccination of both mother and child based on the maternal immunization status, provide vaccination if indicated <ul style="list-style-type: none"> <li>Mother: when it is safe to be administrated</li> <li>Child: where the child may have exposure risk during or after pregnancy</li> </ul> </li> </ul>

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UK Health Protection Agency: The role of the midwife in increasing immunisation uptake, 2011

**Table 4. Areas of knowledge for immunization practitioners**

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**12 core areas covered by basic training**

1. The aim of immunization: national policy and schedules
2. The immune system and how vaccines work
3. Vaccine preventable diseases
4. The different types of vaccines used and their composition
5. Current issues and controversies regarding immunization
6. Communicating with patients and parents
7. Legal aspects of vaccination
8. Storage and handling of vaccines
9. Correct administration of vaccines
10. Anaphylaxis and other adverse events
11. Documentation, record keeping and reporting
12. Strategies for improving immunization rates

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**Areas included in update training**

- Current issues in vaccination
- Recent epidemiology of VPDs
- Any changes to the National Immunization Schedule
- Any changes to legislation relevant to vaccination
- Anaphylaxis recognition and management
- Review of current practice and identification of areas for improvement
- Q&A session for commonly encountered problems in practice

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UK National Minimum Standards for Immunisation Training, 2005

By contrast, the role of midwives in promoting immunization is not well defined in Japan. The standards of midwifery practice listed in the core competencies of midwives stated by the Japanese Midwives Association (2010) do not include immunization-promoting activities. Since the standards of the national examination for midwifery license by Ministry of Health, Labour and Welfare (2013a) contains childhood immunization as a subordinate category, immunization related topics are sure to be covered in the curriculum of pre-service education. However, the learning opportunities become limited after graduation unless the midwives are involved in pediatric service. Responding to the recent increasing need of promoting immunization in the perinatal period, the Japanese Midwives Association launched an in-service midwives' training program for in 2012. Nevertheless, obtaining and updating the knowledge and skills for promoting immunization still depend on individual efforts of midwives or the policy of health facilities they work for.

### **Midwives' perceptions and attitudes toward immunization**

Several studies pointed out that midwives have particular perceptions and attitudes toward childhood vaccination compared to other health care providers. According to an interview study with physicians and midwives by Dube, et al. (2013), all interviewees of physician were in support of vaccination programmes but the midwives' views were more mixed. When the physicians explain about childhood vaccination to parents, they are in a position of actively promoting vaccination but the midwives tend to leave the decision to parents. The most of midwives deemed that the timing of initial vaccination is too early in life. In addition, some midwives viewed that vaccination is not included in their practice and had no opportunity to discuss about vaccination with parents. Another interview study with four different types of health care providers, namely, physicians, nurses, midwives, and chiropractors (Bean & Catania, 2013) found that none of the midwives and chiropractors fully supported the national vaccination programs. All midwives and chiropractors were either opposed or conditionally supported vaccination. Similarly, a questionnaire survey by Leask, et al. (2008) showed that the midwives were more likely to have concerns about the additives in vaccines as well as simultaneous administration compared to other health care providers. Moreover, Lee, Saskin, McArthur, and McGeer (2005) reported that 56% out of 111 midwives in the survey were pro-vaccines and only 24% were proactive in promoting vaccination to their clients.

The fore cited Dube, et al. (2013) noted the gap between physicians and midwives in their attitudes towards vaccination could be rooted in the different tendencies of "informed consent" and "informed choice". Physicians tend to practice "informed consent" based on legal, ethical and administrative compliance attached to biomedical ethics. Particularly, the risks of persecution they face give additional weight to the legal component. However, midwives are prone to facilitate "informed choice" embedded in midwifery philosophy, which is grounded in a recognition of the natural process of pregnancy and childbirth. The authors claim that since the key principals of this philosophy are informed choice and empowerment, midwives take a role of information provider by way encouraging women's individual decision. However, it is pointed out that the different views between physicians and midwives on their role and responsibilities in promoting vaccination sometimes lead to a biased information delivery. For examples, physicians might not listen and respond enough to parents' concerns or even refuse to dialogue with the clients who may be reluctant to vaccinate with the firm commitment to take a promotional role in vaccination. In contrast, midwives

are apt to present pros and cons information to parents in order to take the role of neutral information provider but the cons information is not always scientific evidence-based. The authors emphasize that both physicians and midwives should look back at their ways of information delivery on childhood vaccination with awareness of the different tendencies (Dube, et al., 2013).

As Dube, et al. (2013) indicated, the perceptions and attitudes of health care providers toward immunization can vary depending upon the profession, yet this is not really explored in Japan. In fact, no Japanese article focused on midwives' response to immunization was found. In the interview with some Japanese in-service midwives done by the researcher preparatory for the present study, no one was skeptical or negative about immunization. While Dube, et al. (2013) indicated the midwives' being less actively involved in immunization is rooted in midwifery philosophy, it is not yet demonstrated that the particular perceptions and attitudes observed among midwives are common to all countries.

### **Preliminary Study**

Prior to the development the research proposal of the present study, a questionnaire survey of mothers with infants was conducted in order to explore the possible interventions (Endo, 2014). The following is the summary of the survey findings.

#### **Study summary**

The aim of the survey was to clarify the factors influencing parental decision-making for early childhood immunization and immunization uptake during the recent transition period of Japan's national immunization program. The survey was conducted from May to July in 2013 at two hospitals in Tokyo, Japan. The respondents were mothers who had infants aged six months to less than one year. The survey asked the mothers to recall their immunization activities during the first six months. A questionnaire consisted of 18 items and was developed based on the conceptual framework of Health Belief Model (Becker, 1974). The questionnaire particularly focused on the mothers' information collection process, the obstacles they encountered, and the determinants of their decision-making. The questionnaire also included 12 quizzes to assess mothers' knowledge on VPDs.

The response rate was 94.6% with 316 valid responses. Initial immunization coverage of the infants was 90% or higher for the four routine vaccines (Hib, PCV, DPT-IPV, BCG), but the rate dropped for the two voluntary vaccines of rotavirus infections (73.4%) and HB (28.2%). The main reasons for unvaccinated of HB vaccine related to insufficient knowledge or information of the disease, such as "no infected close relatives", "anxiety caused by lack of knowledge", and "not informed".

Maternal demographic variables, which were associated with the initial vaccination coverage for their infants, were: parity, academic background, working experience and monthly expenses for the infant. Namely, the first child was vaccinated more than the second child or above. The mothers with high educational background (college degree or higher) and had a job before pregnancy initiated a greater number of vaccines for their infants. Additionally, the family, which spent more than ten-thousand yen a month for the infant showed the higher coverage of voluntary vaccines. Other associated variables were: timing of information collection, number of information sources and knowledge about VPDs. The mothers who began information collection by the time of one-month checkup initiated a greater number of vaccines for their children. Similarly, the infants whose mothers had a greater number of information sources and had the higher score on the knowledge test tended to

receive more voluntary vaccines.

The majority of respondents obtained vaccination-related information at hospitals and more than one-third reported that physicians were their main advisor on immunization. Only 10.8% of mothers recognized nursing personnel (nurse, midwife and public health nurse) as their main advisor. Half of the respondents sought the information through the Internet. The amount of information and knowledge of mothers largely affected the initial immunization coverage of their infants. The study concluded that the role of health care provider is crucial in providing correct information in appropriate timing for parents.

#### Implications for the present study

The survey result shows that early information provision for parents was the key to initiate the full-range of vaccines for their infants in appropriate timing. The main impediment for the completion of six initial vaccines was the lack of information rather than negative beliefs in immunization or concerns about vaccine safety. Consequently, the role and responsibility of health care providers as the main information source were highlighted.

In order to enable effective information delivery, all medical professions involved in perinatal care need to play a promoting role for immunization in a timely manner. Among these professions, midwives are in the position to be able to approach pre and postpartum women and their families at the earliest stage. Despite being in the optimal position, Japanese midwives are not fully aware of their potential impact as immunization promoters. Utilizing midwives more effectively in promoting immunization could lead to reducing the case of missed opportunity particularly for initial vaccination. Thus, the present study focuses on improving midwives' capacity to fulfil the role of information provider through developing an educational programme and examining its effectiveness.

## **Methods**

### **Study design**

This is a controlled study without randomization. The participants were allocated on a facility-by-facility basis. The data was collected from both midwives and mothers in each participated facility.

As table five shows, the intervention group midwives were provided an hour lecture, an A4 size two-sided flyer, a list of information resources, and a published booklet. The control group midwives were not given the lecture and encouraged to self-learn with the distributed materials. Both groups were offered e-mail consultation on an as-needed basis or face-to-face consultation at least twice during the two months of data collection period.

The study timeline is shown as figure one.

### **Study hypothesis and outcomes**

The midwives who receive the educational program would become more active in immunization-promoting activities due to increasing the latest knowledge and decreasing the difficulties in providing information.

The mothers, who are provided immunization-related information during pre and postpartum period by midwives, would become more aware of immunizations and build a positive intention for initial vaccination of their infants.

Based on the above hypothesis, the outcomes of the present study were set up both for midwives and mothers. As for the maternal outcome measurement, the exact date for initial vaccination of all participants' infants could not be traced within the limited study period. Therefore, mothers' intention of initial vaccination for their infants at the time of one-month checkup was investigated with a questionnaire. In addition to that, the initial vaccination status of the infants at aged two-months was followed with a return postcard.

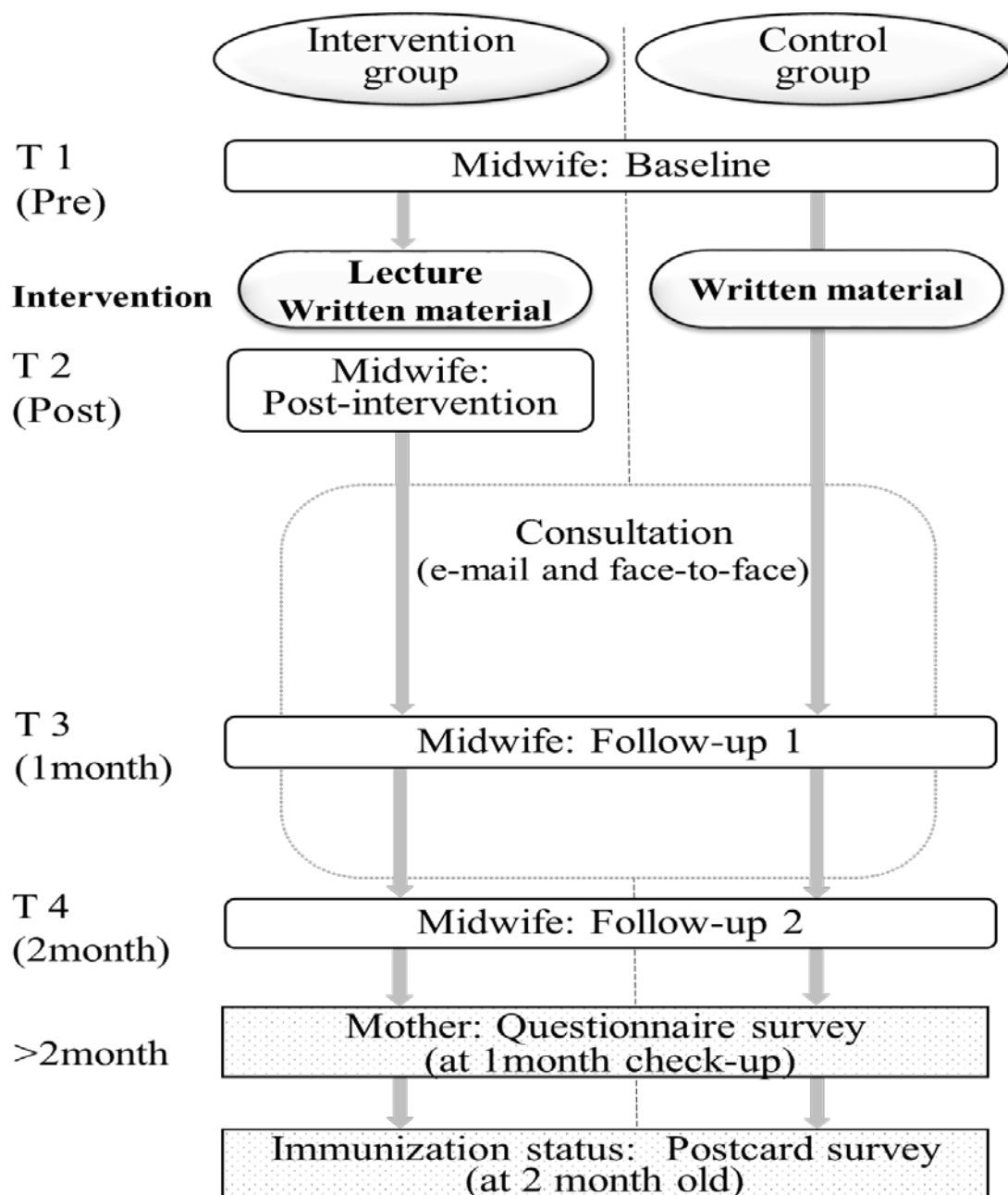
The following is the primary and secondary outcomes for midwives and mothers.



**Table 5. Intervention detail**

	Lecture	Flyer (Appendix 13)	Information resource list (Appendix 14)	Booklet	Consultation e- mail/face-to-face
Intervention group	✓	✓	✓	✓	✓
Control group		✓	✓	✓	✓

**Figure 1. Time line of intervention and outline measurement**



**Primary outcome.***Midwives.*

The amount of change in the frequency of immunization-promoting activities between the periods of baseline and follow-up 1 (T3) is larger in the intervention group compared to the control group.

*Mothers.*

The proportion of mothers who intend to immunize voluntary vaccines (HB and rotavirus infections) for their infants at the time of one-month checkup is higher among those who received pre and postpartum care from the intervention group midwives compared to those who were cared for by the control group midwives.

**Secondary outcome.***Midwives.*

1. The amount of change in the knowledge test score between the periods of baseline and follow-up 1 (T3) is larger in the intervention group than the control group.
2. The amount of change in the willingness to provide immunization-promoting activities between the periods of baseline and follow-up 1 (T3) is larger in the intervention group than the control group.
3. The amount of change in the difficulties to provide immunization-promoting activities (hereafter difficulties) between the periods of baseline and follow-up 1 (T3) is larger in the intervention group than the control group.
4. The primary outcome (frequency of immunization-promoting activities) and the secondary outcomes 1.2.3. in the intervention group at the periods of follow-up 1 (T3) and follow-up 2 (T4) remain at the same level or show an improvement.

*Mothers.*

1. The mothers who received pre and post-partum care from the intervention group midwives are more aware of the need for their rubella immunization than those cared for by the control group midwives.
2. The mothers who received pre and post-partum care from the intervention group midwives are

more frequently provided the information and advice on immunization than those cared for by the control group midwives.

3. The mothers who received pre and post-partum care from the intervention group midwives take more preparatory action (the selection of a health facility for initial vaccination) than those cared for by the control group midwives.
4. The mothers who received pre and post-partum care from the intervention group midwives have a higher knowledge test score than those cared for by the control group midwives.
5. The mothers who received pre and post-partum care from the intervention group midwives show a higher proportion of timely initial vaccination of their infants at aged two months than those cared for by the control group midwives.

#### **Participants.**

##### **Target facility.**

Hospitals, which provide both obstetric (prenatal checkup, delivery assistance, and postpartum checkup) and pediatric services (immunization and growth development checkup), were invited to participate in the present study. In addition, as the educational program of the present study was developed based on the recommended schedule of the Japan Paediatric Society, the childhood immunization practice in participating facilities should have been in line with the policy of the Society.

##### **Inclusion criteria.**

###### *Midwives*

1. Who had opportunities to provide immunization-promoting activities for pregnant or postpartum women at childbirth class, outpatient department (OPD) or inpatient department (IPD)
2. Who were able to attend an hour educational program and to response the multiple questionnaires at baseline, post-intervention and follow up
3. Who agreed to participate in the whole process of the study with written consent after receiving an explanation of the study purpose and method

The midwives at the participating facilities who fulfilled the above criteria were included regardless of the years of clinical experience, the frequency of immunization-promoting activities, or

the participation in immunization-related trainings.

### *Mothers*

1. Who visited the hospitals for the one-month checkup of their infants
2. Who were able to understand the Japanese questionnaire and to respond it in Japanese
3. Who agreed to participate in the study with oral consent after receiving an explanation of the study purpose and method

The mothers who met the above criteria were included regardless of their nationality. Since the immunization program is uniform throughout the nation, the participants' current residential address was not taken into account. The gestational age and the birth weight of their infants were also irrelevant for the present study as they do not negatively affect the timing of initial vaccination.

### **Sample size.**

#### *Midwives*

The sample size for midwives was determined based on the difference in the proportion of the primary outcome (the amount of change in the frequency of immunization-promoting activities) between the two arms before and after the intervention. However, the preceding provider education studies on immunization did not include the practice of participants in their outcome indicators. Thus, the following educational intervention studies for nursing personnel outside of immunization were used as the reference.

A three-arm controlled study of breast cancer education for midwives by Kataoka, Obayashi, and Suzuki (submitted) employed the amount of change in the implementation rate of educational activities as the outcome. The difference of the amount of changes between the intervention and the control groups at one month and at three months after the awareness program were 36% and 23%, respectively. Moreover, a before-after study of provider training for smoking cessation (Borrelli, Lee, & Novak, 2008) indicated a 40% of increase in the change of counseling behavior among home health care nurses at the six months follow-up, compared to pre-training.

On the basis of these studies, the difference of the primary outcome for the present study was assumed more than 30%. The required sample size was 32 midwives for one group with a significance

level of five % ( $\alpha = .05$ ) and a power of 80% ( $\beta = .2$ ). Adding 20% of expected drop-out rate to the calculation, the optimal sample size was estimated 76 in total (38 midwives for one group).

### *Mothers*

The sample size for mothers was calculated with the deference in the proportion of the primary outcome (the intention to immunize two voluntary vaccines [HB and rotavirus infections] for their infants) between the groups of facilities at the one-month checkup.

Among the six vaccines for infants below the age of one, the HB vaccine showed the lowest coverage (28%) in the preliminary study (Endo, 2014) and was considered as the less understood vaccine from the local government (Hori, 2014). While the coverage of rotavirus vaccine in the preliminary study was higher (73%) than the estimate of national average (45%) (Ministry of Health, Labour and Welfare, Japan, 2013b), about 40% of parents had difficulty in making a decision about this vaccine due to a scheduling conflict and the expensive self-pay cost (Endo, 2014).

The limited number of studies employed patients' immunization rate as the outcome of the educational intervention. A before-after study by Uskun, et al. (2008) showed a seven % increase on average in the four recommended vaccines after the provider training. A three-arm RCT examined the effectiveness of an educational program for parents during the perinatal period traced the coverage of three voluntary vaccines at aged three months. The result indicated a 21% of increase in the pre-partum education group and a 30% of increase in the post-partum education group, compared to the control group (Saitoh, et al., 2013).

On the basis of these studies, the difference of the primary outcome of the present study was assumed more than 20%. The required sample size was 93 mothers for one group with a significance level of five % ( $\alpha = .05$ ) and a power of 80% ( $\beta = .2$ ). The response rate was expected to be 90% based on the results of the preliminary study, thus the optimal sample size was estimated 204 in total (102 mothers for one group). The number of respondents in each facility was calculated based on the percentage of the participating midwives.

## **Intervention**

### **Educational program**

#### **Purpose of educational program.**

1. To obtain the necessary knowledge and up-to-date information in order to provide immunization-promoting activities for pre and postpartum women and their families
2. To increase the opportunities to provide immunization-promoting activities during perinatal and early childhood periods by obtaining the knowledge

#### **Goal of educational program**

were to be able to explain the:

1. need for immunization
2. recommended vaccines of mothers, infants and their families
3. optimal timing for the recommended vaccines
4. need for voluntary vaccines
5. effectiveness and adverse event of immunization

The term “mothers” here includes women in pregnancy and postpartum period, and “infants” means the children aged less than six months.

#### **Method of educational program.**

The program was a 75-minute lecture including a question and answer session. A fifteen-minute discussion was added at the end of the lecture with the intent of promoting motivation to put the obtained knowledge into practice. Since the participating midwives were not a vaccinator, vaccine handling and administration practice were excluded from the program. Additionally, midwives in general are skilled at information delivery as they have frequent opportunities to provide consultation and guidance in their daily practice, thus communication skill practice was not included in the program.

The form of educational program was a face-to-face lecture but not e-learning or DVD material. The reasons for not choosing these self-learning tool are: the chance for low completion of the non-mandatory program, unable to respond immediately to participants' questions, and the potential of difference in IT environment among the participants. An interview with midwives prior to developing

the program indicated that their expectations of a program were: “a concise lecture totally around one hour maximum”, including “practical content” and “readily available information and written materials”. The program was designed with incorporating these needs.

The adult learning theory of Knowles (1980) describes the characteristics of adult learners as “increasing self-directness”, “accumulated experience becomes a rich resource for learning”, “readiness to learn is based on the tasks of their social roles”, and “aspiring to immediate apply obtained knowledge and skill” (pp.43-44). These characteristics are thought to be common to the participated in-service midwives in considering them as adult learners. The “increasing self-directness” suggests that the participants supposed to have acquired a certain level of self-learning skill. Besides, many of the midwives were assumed to be in “readiness to learn” about immunization responding to recent rubella outbreak in Japan (Ujiie et al., 2014). If learners are in readiness to learn the topic and have a self-learning skill, they should be able to complement the additional knowledge by their own effort after receiving a short lecture. Thus an information source list of relevant web-sites was distributed to all participants in order to facilitate their self-learning.

As obtained knowledge can be retained by use in practice, the program encouraged the participants to take advantage of every opportunity to provide information for any length of time. In order to apply the obtained knowledge into practice immediately after the program, an educational flyer designed for use in consultation and guidance was provided on request. The flyer was developed on the basis of the content of the educational program including key messages on early-childhood immunization.

With providing immunization-promoting activities in clinical place, it was expected that the participants might have questions after the program. In order to support their activities, the researcher offered as-needed e-mail consultation and face-to-face consultation at least twice during the two months of data collection period for both groups of participants.

### **Content of educational program.**

#### *Lecture*

The program was developed by the researcher based on the existing domestic and overseas training materials (Australian Government, Department of Health, 2000; The Health Protection Agency, U.K, 2005; Immunisation Advisory Centre (IMAC) NZ, 2013; WHO, 2013; Foundation of

Vaccination Research Center, 2013) and modified it to suit the actual practice of midwives in Japan.

Compared to pre and postpartum periods, the level of interest of parents and available time for immunization-promoting activities are different. Therefore, the information provided in pregnancy period focuses on the following one to four, and the detailed information five to ten is additionally given in postpartum period.

Pregnancy period:

1. Need for early childhood immunization
2. Rubella antibody and the need for vaccination
3. Timing for initial vaccination
4. Preparation for initial vaccination

Postpartum period: in addition to the above 1. to 4.

5. Voluntary vaccines
6. Live vaccine and inactivated vaccine
7. Recommended schedule and simultaneous vaccination
8. Completion of vaccination
9. Adverse event and side effect
10. Record keeping

An expert in the relevant field checked the validity of the program content. The feasibility of the program and the validity of the evaluation tool were assessed by a pilot test with seven researchers in the fields of midwifery and nursing. The program was finalized after incorporating their advice and the test results.

The details of the program are in appendix 12.

#### *Motivational session*

The program included a small discussion session at the end of the program, which encouraged the participants to think about the actual implementation of immunization-promoting activities in their daily work. The purpose of this discussion was to motivate the individuals to initiate (or enhance) the activities for putting the program content into practice.



The participants discussed the following three points.

1. The optimal timing and available time for providing immunization-promoting activities for clients during pregnancy to postpartum period.
2. The minimum information needed to be provided above one.
3. The utilization of the flyer provided by the researcher (Appendix 13)

#### **Flyer for promoting activities.**

A flyer designed for using immunization-promoting activities was provided for all participants as a handout (Appendix 13). The lecture for the intervention group was also given based on the items of the flyer. The flyer was developed by the researcher and checked by an expert in the relevant field.

All participated facilities were offered an additional supply of the flyer for their own use. Two facilities of the intervention group decided to distribute the flyer for their clients. Prior to the distribution, the original flyer was modified to respond to the request from each facility. The modified flyer was a simplified version and added a recommended vaccination schedule of each facility.

#### **Materials for self-learning.**

*A list of information source (Appendix 14)*

In order to facilitate the participants' self-access, a list of immunization related web-sites were provided for both groups of participants. An expert in the relevant field checked the adequacy of the list, to make sure the list covered all important information sources.

*A booklet for nursing personnel*

A published booklet by a non-profit organization of "Know★VPD!" was provided for both groups of participants as a handout. The booklet was designed particularly for nursing personnel such as public health nurses, midwives and nurses. The recommended vaccination schedule by Japan Paediatric Society at the back of the booklet was referred to in the lecture for intervention group.

#### **Program implementation.**

The researcher went to each participating hospital to provide the lecture and the data collection. A room equipped with a table and chairs for the lecture was provided by the facility and arranged as

described in Appendix 11. A handout (flyer), self-learning materials (booklet and information source list) and a pen were distributed for each participant.

The same lecture was to be given multiple times at each facility until all enrolled midwives to attend. Each lecture needed to be delivered by following the same procedure as it was planned for ensuring the effectiveness of the program. This is what it is called the fidelity of intervention (Chen, 2005). However, a time-dependent change could occur in the provider performance by the repetition of lecture delivery. Additionally, since the lecture took place at the on-site setting, uncontrollable factors affecting the fidelity of the program were expected. In order to monitor the fidelity of the program, two-thirds of the lecture was assessed by an observation of a third party with a fidelity checklist (Appendix 15). The checklist included Dane and Schneider's (1998) five aspects to assess the intervention fidelity: "adherence", "exposure", "quality of delivery", "patient responsiveness" and "program differentiation" (Table 6). Each item was measured with a five-point Likert scale with five (*strongly agree*) to one (*strongly disagree*). The total score possible was 25. The raters returned the completed checklist either putting it in a collection box or sending it by mail within a week of the observation.

**Table 6. Five aspects of fidelity**

Adherence	The extent to which the program components were delivered as prescribed
Exposure	The number, length, and frequency of sessions received by participants
Quality of delivery	The extent to which the facilitator implemented program as planned (including attitude, enthusiasm, and preparedness)
Participant responsiveness	The level of engagement of the participants
Program differentiation	Any particular factors influence on the effective implementation of program

### **Additional support for midwives**

#### *Newsletter distribution*

A newsletter was distributed to all participants around one month after the intervention as a reminder for immunization-promoting activities. The newsletter included the up-to date information of immunization and the details about the topics referred in the lecture.

#### *Face-to-face consultation and e-mail access*

The both groups of midwives were offered the opportunities to ask questions to the researcher

face-to-face at least twice during the data collection period. The researcher visited each facility around one and two months after the intervention. The face-to-face consultation was expected to have a positive effect for reminding the midwives to provide immunization-promoting activities. Additionally, the participants were informed of the researcher's e-mail address and offered e-mail access as needed.

### **Procedure for study implementation.**

#### **Preparation.**

With access to the Internet hospital search sites, the researcher made a list of the potential facilities, which met the inclusion criteria in the accessible regions, and approached the person responsible in each facility by phone for the first contact. After obtaining permission, the researcher sent the study outline and the related documents (Appendix 1, 2, 5, 6, 10, 11, 12) to the director of nursing or the responsible for in-service training at each facility.

After the facility agreed to enrol in the study, the researcher visited the contact personnel to explain the details of the study. The childhood immunization practice in each facility was checked if it was in line with the policy of Japan Paediatric Society. The facilities that did not practice under the Society's recommended schedule were excluded at this stage.

#### **Data collection.**

##### *Midwives*

The researcher asked for study participation from midwives during a regular staff meeting at each facility. In order to contact all potential participants, additional briefing sessions were arranged for those who did not attend the staff meeting. A signed consent form was obtained from each midwife who agreed with participation in the study. The control group midwives were required to fill out the baseline questionnaire immediately after signing the consent form and were provided the self-learning materials after that.

The educational program was provided multiple times with a small group in each intervention facility. The intervention group midwives were required to fill out the baseline and post-intervention questionnaires immediately before and after the educational program.

The both groups of midwives were required to fill out the follow-up questionnaires one and two month after the educational program or the material distribution. The drop-off and pick-up method

was applied to the follow-up questionnaires.

### *Mothers*

The researcher approached the mothers who visited the paediatric OPD for the one-month checkup and with a written request form invited them to participate in the study face-to-face. Those who agreed with the participation were given the self-administrated questionnaire and requested to fill out the questionnaire using the waiting time at OPD. The completed questionnaire was collected by the researcher or dropped in a collection box equipped at the OPD.

No written consent form was used, since responding to the questionnaires was considered as the consent for study participation.

In addition to the above, a stamped postcard addressed to the researcher with a personal information protection seal was given at the time for the questionnaire survey to all respondents.

### **Data collection period**

The initiation of study differed according to the facility. The entire process of data collection for both midwives and mothers in the five facilities ranged from June, 2014 to May, 2015.

### Evaluation tools

The evaluation of the present study was designed on the basis of the four levels of evaluation model by Kirkpatrick (2005). Table 7 shows the measurement items and the means for evaluation at each level.

#### For midwives.

##### *Baseline, post-intervention, and follow-up questionnaires (Table 8)*

The following six perceptions, behaviors and knowledge (1. through 6. listed below) were measured with questionnaires (see Appendix 6, 7, 8). The data from the intervention group was collected four times: (a) prior to educational program (baseline: T1), (b) immediate after the program (post-intervention: T2), (c) at one month post program (follow-up one: T3), and (d) at two months post program (follow-up two: T4). As the control group was provided with self-learning materials instead of the educational program, the data were collected three times: (a) at the time of material distribution (baseline: T1), (c) at one month (follow-up one: T3), and (d) at two months after the distribution (follow-up two: T4). As table 7 shows, both groups were asked the same questions at baseline and follow-ups but the post-intervention questionnaire for the intervention group also included the evaluation items about the program (lecture) (Table 7, Level 1. Reaction). All questionnaires were anonymous using a self-administrated format.

#### 1. Frequency of immunization-promoting activities

Midwives selected the number of opportunities they could possibly have provided immunization-promoting activities in their daily work for the past week. The total possible scores ranged from eight to 24 (the question asks the number of promoting activities on eight types of opportunities with three levels of frequency). The eight types of immunization-promoting opportunities were: (a) childbirth class in prenatal period; (b) prenatal checkup at OPD; (c) prenatal admission to IPD; (d) postpartum admission to IPD; (e) postpartum breastfeeding consultation; (f) one month postpartum checkup at obstetric OPD; (g) one month postnatal checkup at pediatric OPD; (h) parenting group program in early-childhood. The three levels of frequency were: (a) none, (b) one to three times in the week, (c) more than four times in the week.

Providing immunization-promoting activities in this question was considered as mentioning

something about immunization regardless of the content and the form of activities. Either of the following activities was counted as providing the activities, namely ‘encouraging immunization’, ‘distributing any kind of written material’, ‘explaining the detailed information’, and ‘having a face-to-face consultation’.

## 2. Difficulties in providing immunization-promoting activities

A 100mm of Visual Analogue Scale (VAS) was used for metrical evaluation of the difficulties in providing immunization-promoting activities. The scale was anchored by “no difficulty” (score of zero) to extremely difficult (score of 100 [100 mm scale]). Additionally, in order to determine which specific topic the midwives felt were difficult to explain, the level of difficulty of the main topics of immunization-promoting activities covered in the lecture were measured with a five-point Likert scale of very easy to very difficult. The included five topics are “age appropriate vaccines”, “voluntary vaccines”, “vaccination schedule”, “herd immunity” and “adverse event”.

## 3. Perception for immunization and willingness of promoting activities

The six items, which assess the midwives’ attitude towards immunization and promoting activities were included in all the questionnaires. All questions were asked with a five-point Likert scale of strongly disagree to strongly agree. There seemed to be no existing literature focused on Japanese midwives’ views on childhood immunization. Thus, the questions were developed by reference to some qualitative studies in other developed nations (Bean & Catania, 2013; Leask, et al., 2008; Lee, et al., 2005) and also the interview findings with Japanese in-service midwives collected by the researcher.

The questions included the impediment factors for providing immunization-promoting activities derived from the interview, namely, “I do not have enough knowledge on immunization”, “I have not up-dated information on immunization”, and “I have no time for immunization-promoting activities”. Since the educational program was designed knowledge-based and included a discussion for promoting motivation to put the obtained knowledge into practice, these items were expected to improve after attending the program.

In order to assess the presence and extent of the midwives negative or positive perception towards immunizations, the questions of “natural infection is better than immunization”, “children

**Table 7. Outcome measurement at each level of Kirkpatrick's evaluation model**

Level	Descriptions	Outcome measurement	
		Measurement items	Means for evaluation
<b>1. Reaction</b>	How the participants react to the program	• Program evaluation	Questionnaire for midwives
<b>2. Learning</b>	The extent to which the participants change attitudes, improve knowledge, and/or increase skill as a result of attending the program	• Knowledge test • Difficulties of providing promoting activities • Perception for immunization and willingness of promoting activities	Questionnaire for midwives
<b>2. Behaviour</b>	The extent to which the participants change in behaviour has occurred because they attended the program.	• Frequency of providing promoting activities • Frequency of receiving support from midwives	Questionnaire for midwives Questionnaire for mothers
<b>3. Result</b>	The final results that occurred because the participants attended the program.	• Intention for immunizing of 6 early-childhood vaccines • Timeliness of initial vaccination	Questionnaire for mothers Postcard survey for mothers

**Table 8. Measurement items for midwives at baseline, end-line, and follow-up**

		Measurement items					
		Difficulties	Perception Willingness	Frequency of activity	Knowledge test	Program evaluation	Demographic information
<b>Baseline data (Pre-test)</b>							
Intervention group	Prior to lecture	✓	✓	✓	✓	×	✓
Control group	Prior to material distribution	✓	✓	✓	✓	×	✓
<b>Post-intervention data</b>							
Intervention group	Immediate after lecture	✓	✓	×	✓	✓	×
<b>Follow-up data</b>							
Intervention group	1 month after lecture	✓	✓	✓	✓	×	×
	2 months after lecture	✓	✓	✓	✓	✓	×
Control group	1 month after distribution	✓	✓	✓	✓	×	×
	2 months after distribution	✓	✓	✓	✓	✓	×

should be given all age appropriate vaccines” and “I would like to recommend immunization to my clients” were added. The effectiveness of the educational program ‘change of these perceptions’ was examined by comparing the results of before and after the program.

#### 4. Knowledge test

Twenty questions about immunization and VPDs covered in the educational program were included in each of the questionnaires in order to assess the change in knowledge level. All questions were developed by the researcher and checked by an expert in the relevant field as to their content validity. The face validity of the questions was assessed by a pilot test with seven researchers in the fields of midwifery and nursing. Three-option responses of “correct” “incorrect” and “do not know” were applied in this question and the total score of right answers was considered to indicate the level of obtained and retained knowledge.

#### 5. Demographic data

The collected data included the following: “the years of working experience as midwife”, “current workplace (OPD or IPD)”, “past experience of participation in immunization-related training”, “age”, and “academic background”.

#### 6. Program evaluation

The post-test questionnaire for the intervention group included six items to assess the effectiveness of the lecture in the light of meeting the participants’ satisfaction and needs. The participants responded immediately after the lecture. They used a five-point Likert scale regarding to what extent they agreed with the following items: “the lecture was easy to understand”, “the lecture was too short”, “the content fulfilled their expectations”, “the facilitator explained clearly”, “what they learnt was practical for their daily practice”, and “encourage others to participate this program”.

The final questionnaire at two months after for both groups included three items to assess the effectiveness of the program on raising the participants’ awareness using a close-ended question (yes or no). All participants were asked whether they, “had a chance to read the distributed booklet”; “had a chance to access any of the web-site on the distributed information resource list”; and “more interest in immunization than before”.



### **For mothers.**

#### *A questionnaire and a postcard survey*

The following five intentions, behaviors and knowledge 1. through 5. were measured with a questionnaire (see Appendix 9). The questionnaire aimed to assess to what extent the participating midwives delivered the obtained information to their clients. Therefore, the timing for data collection was scheduled two months after the intervention in order to the midwives to have sufficient time for providing immunization-promoting activities. The data collection with the questionnaire was conducted taking the occasion of one-month checkup for the infants. The questionnaire was an anonymous self-administrated format.

In addition to the questionnaire survey, the initial vaccination coverage was traced by a postcard survey at the age of two months. A stamped postcard addressed to the researcher was distributed to all respondents at the same time as the questionnaire survey. The researcher requested the mothers to return the postcard anonymously regardless of the immunization status of their infants at the age of two months.

#### **1. Intention to immunize**

As the timing of initial vaccinations varied according to the vaccine, tracing the completion of six initial vaccinations was not feasible within the study period. Instead of the coverage, mothers' intention to seek immunization for their infants in advance of the first vaccination was used as a proxy outcome indicator. The questionnaire asked which of the six initial vaccines mothers to intend to initiate for their infants at the time of one-month checkup.

Additionally, the questionnaire included an item to assess whether, according to the test results during pregnancy, mothers recognized their susceptibility to rubella and the need for rubella vaccination. The respondents were asked to choose one of the five responses: "no need to immunize (as not susceptible to rubella)"; "had immunized within a month of post-partum period"; "would immunize in the near future"; "not decided yet" and "do not know my susceptibility to rubella".

#### **2. Preparation for initial vaccination**

Usually, initial vaccination is carried out either at six weeks for the first dose of rotavirus vaccine as single vaccination or at the age of two months for simultaneous vaccination with multiple vaccines

in Japan. The progress on the mothers' selection of a health facility for initial vaccination was asked as an indicator to determine whether mothers had begun to take preparatory action. The timing of the data collection at one-month checkup is assumed to be the time for parents to select a facility for initial vaccination. The respondents specified their progress of facility selection by choosing one of the following as: "already made an appointment", "already selected a facility (not yet booked)", "looking for the facilities (not yet selected one)", "not yet looking for the facilities", and "have no thought to vaccinate the infant".

### 3. Knowledge test

In this study, ten out of twelve questions in the preliminary study were used to assess the mothers' level of knowledge about vaccination and VPDs (Endo, 2014). All questions were developed by the researcher and checked by an expert in the relevant field as to their content validity. The face validity of the questions was confirmed by the preliminary study with 95 % of valid response rate for all the items. Three-option responses of "correct" "incorrect" and "do not know" were applied in the knowledge test and the total score of right answer was considered to indicate the level of knowledge on immunization.

### 4. Immunization-promoting activities by midwives

The questionnaire investigated whether mothers received any immunization-related support from midwives during pregnancy and postpartum period. Five occasions which mothers could possibly have received immunization-related support were listed and the respondents were asked to note if they had received that type of support. The listed occasions were "childbirth class in prenatal period", "prenatal checkup at OPD", "prenatal admission to IPD", "postpartum admission to IPD", and "postpartum breastfeeding consultation". Since the occasions spanned several months over the pre and postpartum periods, recalling the detailed information was thought to be difficult for the respondents. Therefore, at each occasion women were provided a close-ended question form to focus on the presence or absence of the support by midwives.

### 5. Demographic data

The collected demographic data included "the number of children", "employment status before

pregnancy”, “age”, and “academic background”.

#### 6. Postcard survey

The return postcard asked “the exact date for immunization or booking for four initial vaccines scheduled from the ages of two months (Hib, PCV, HB, and rotavirus infections)”. The information of “the date of birth for the infant” was also collected to determine the timing of initial vaccination.

#### **Validity of evaluation tool.**

The questionnaires for both midwives and mothers had a pilot test in order to estimate the time required for filling in and to assess the face validity of the tools. Seven researchers in the fields of midwifery and nursing and three mothers with small children completed the questionnaires and suggested the points that needed to be corrected. The questionnaires were revised incorporating the test results. The average time required for midwives to answer the questionnaire was nine minutes, and the maximum response time for mothers was five minutes.

#### **Data analysis**

All statistical analysis was performed using SPSS statistics version 22 and R statistical software version 3.2.2. Two-sided p-values and an alpha ( $\alpha$ ) level of less than 0.05 were considered statistical significant.

Descriptive statistics were used to summarize the demographic data and each outcome variable. The Fisher’s exact test or the  $\chi^2$  test was used for comparing the nominal data. The t-test or the Mann-Whitney U test was applied for the comparison of the between-group differences in the ordinal and interval scales. Two-way repeated measures ANOVA was used to assess changes overtime for the continuous variables of VAS and knowledge test scores.

#### **Ethical consideration**

The study was implemented with the ethical approval from the Institutional Ethics Review Board (IERB) of St. Luke’s international university and from the IERB of each facility as required.

The potential participants of midwives were given a briefing session and the consent of the participation was obtained with a consent form (Appendix 3). A consent withdrawal form (Appendix

4) was also given to the participants prior to the study. The following (a) to (f) were explained and assured by the researcher in the briefing session and with the written consent form. These were: (a) the study participation is voluntary; (b) the decision of participation and withdrawal will in no way affect the individual; (c) the anonymity and confidentiality of identifying information will be maintained over the whole process of the study; (d) the completed questionnaires will be stored for five years and shredded for disposal; (e) the data are kept in a locked place only accessible to the researcher over the entire study period; (f) the collected data will not be used for purposes other than research, but the result will be reported in the doctoral dissertation and disseminated by presentations in academic meetings and published articles in journals, (g) the control groups were assured to have a similar educational program after the completion of data collection if requested.

The potential participants of mothers were given a face-to-face invitation by the researcher with a written request form. The information of above mentioned (a) to (f) was explained prior to the consent. A written consent form was not obtained as responding to the questionnaire was considered the acceptance.

## **Findings**

### **Midwife**

#### **Participating facilities.**

In total, five facilities in the Kanto and Kansai regions participated in the study. Two hospitals were allocated to the intervention group and three were assigned to the control group. The allocation was done with adaptive allocation method, namely assignment based on an earlier assignment in the order of recruitment. Of two intervention group facilities, one was a 40 bed specialized hospital for obstetric and pediatric services and the other one was a 280 bed general hospital having around 20 clinical departments. Three control group facilities were all general hospitals that had between 10 to 30 departments and 200 to 360 beds. All five facilities provided maternal and child health services including delivery assistance and childhood immunization. The childhood immunization practice of these facilities was in line with the policy of Japan Paediatric Society without a limitation on the number of simultaneous administration of vaccines.

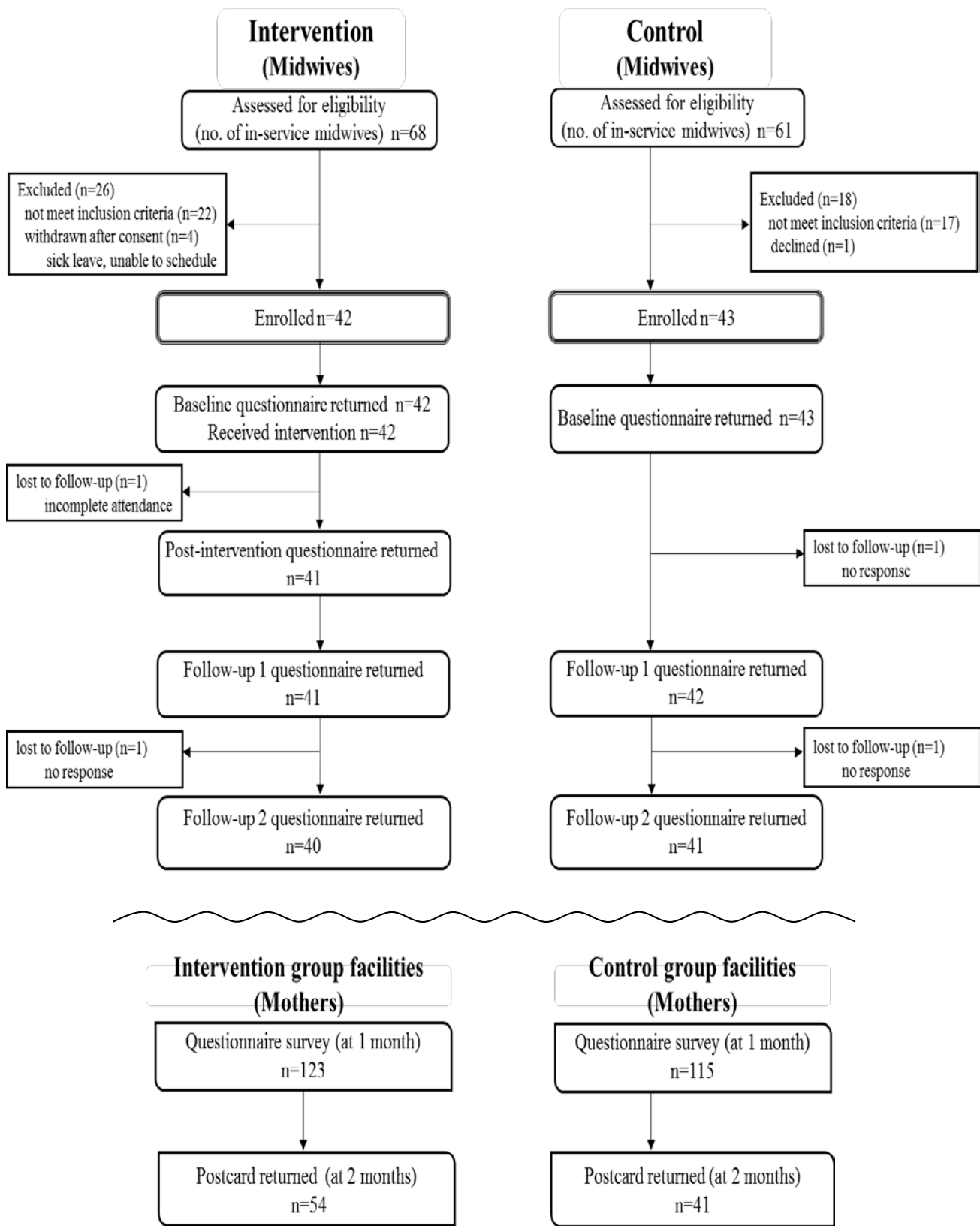
#### **Participant flow.**

As Figure 2 shows, all 129 in-service midwives at the obstetric department of each facility were assessed for eligibility. From among them, 39 were excluded, as they did not meet the inclusion criteria. After obtaining written consent, four midwives in the intervention group withdrew, as they could not meet the scheduled lecture time.

Of those who responded to the baseline questionnaire, four (two in each group) were lost to follow-up (one because of incomplete attendance of the lecture, and three did not respond to the follow-up questionnaires). Thus the final dropout rates of the intervention and the control groups were 4.8 % (two midwives) and 4.7 % (two midwives), respectively.

The analysis was done with the data of enrolled participants (42 in the intervention group and 43 in the control group). The missing values of the lost to follow-up cases were handled with the LOCF (Last Observation Carried Forward) imputation method of substituting the same value as the previously returned questionnaire (European Medicines Agency, 2010).

**Figure 2. Flow diagram**



### Demographic characteristics.

Table 9 shows the characteristics of the participating midwives. Only the item of “current work place” differed between the two groups ( $p < .001$ ). This was due to one intervention group hospital that employs the unfixed staff assignment system so that the midwives change their work place on a daily basis. In each group 14% of midwives had attended an immunization related training within three years. The rest of midwives had either participated in a training over four years ago (9.5% of the intervention group and 2.3% of the control group) or had no immunization training (71.4% of the intervention group and 81.4% of the control group).

**Table 9. Demographic characteristics of midwives (N = 85)**

		Intervention n=42	Control n=43	p
Age (n, %)	20s	11 (26.2)	16 (37.2)	.44 <sup>a</sup>
	30s	16 (38.1)	14 (32.6)	
	40s	7 (16.7)	3 ( 7.0)	
	>50s	6 (14.3)	9 (20.9)	
	NA	2 ( 4.8)	1 ( 2.3)	
Years of midwifery experience (mean, SD) (range)		11.1±8.2	11.0±9.5	.97 <sup>b</sup>
		0.5-35	0.5-35	
Academic background (n, %)	Diploma	19 (45.2)	24 (55.8)	.38 <sup>c</sup>
	Bachelor or higher	21 (50.0)	18 (41.9)	
	NA	2 ( 4.8)	1 ( 2.3)	
Attendance at immunization training (n, %)				.39 <sup>d</sup>
	within 3years	6 (14.3)	6 (14.0)	
	over 4years ago	4 ( 9.5)	1 ( 2.3)	
	none	30 (71.4)	35 (81.4)	
	NA	2 ( 4.8)	1 ( 2.3)	
Current work place (n, %)	OPD	0 ( .0)	2 ( 4.7)	< .001 <sup>d</sup>
	IPD	25 (59.5)	39 (90.7)	
	not fixed	15 (35.7)	0 ( .0)	
	others	0 ( .0)	1 ( 2.3)	
	NA	2 ( 4.8)	1 ( 2.3)	

Note. NA=not available; OPD=Outpatient department; IPD=Inpatient department

<sup>a</sup> Mann-Whitney U test

<sup>b</sup> student's t-test

<sup>c</sup>  $\chi^2$  test

<sup>d</sup> Fisher's exact test

### **Primary outcome.**

The change in the mean score of primary outcome “frequency of immunization-promoting activities by midwives” (hereafter frequency) is shown in Table 10.

The baseline data did not show a significant difference between the two groups (see Table 10). The implication of the total score around eight at baseline (T1) was that the majority of midwives had not provided immunization-promoting activities on any of the eight opportunities prior to the intervention. The mean scores remained at the same level at T3 and T4 in both groups with no significant difference between the groups (see Table 10).

Of the eight types of opportunities, the most frequent opportunity for the midwives to provide the promoting activities was postpartum admission period at IPD. This trend was the same from T1 through T4 in both groups, and probably attributed to the fact that the most of the participants were being assigned to the obstetric IPD at the time of the study.

In response to the lecture, the intervention group facilities made a decision to distribute the flyer to their clients, which was a modified version of the one used in the lecture. All facilities were offered an additional supply of the flyer, but only the intervention group facilities accommodated the offer.

The modified flyer was a simplified version and added a recommended vaccination schedule of each facility. The flyer was distributed at the time of prenatal checkup in OPD and during postnatal admission to IPD by midwives and other health care providers.

### **Secondary outcome.**

#### ***Difficulties.***

The level of difficulties of midwives to provide immunization-promoting activities was investigated using a 100mm VAS. A five-point Likert scale was used for five main topics of the promoting activities.

#### ***Difficulties score***

The change in the mean score of difficulty based on the VAS is shown in Table 10 and Figure three.

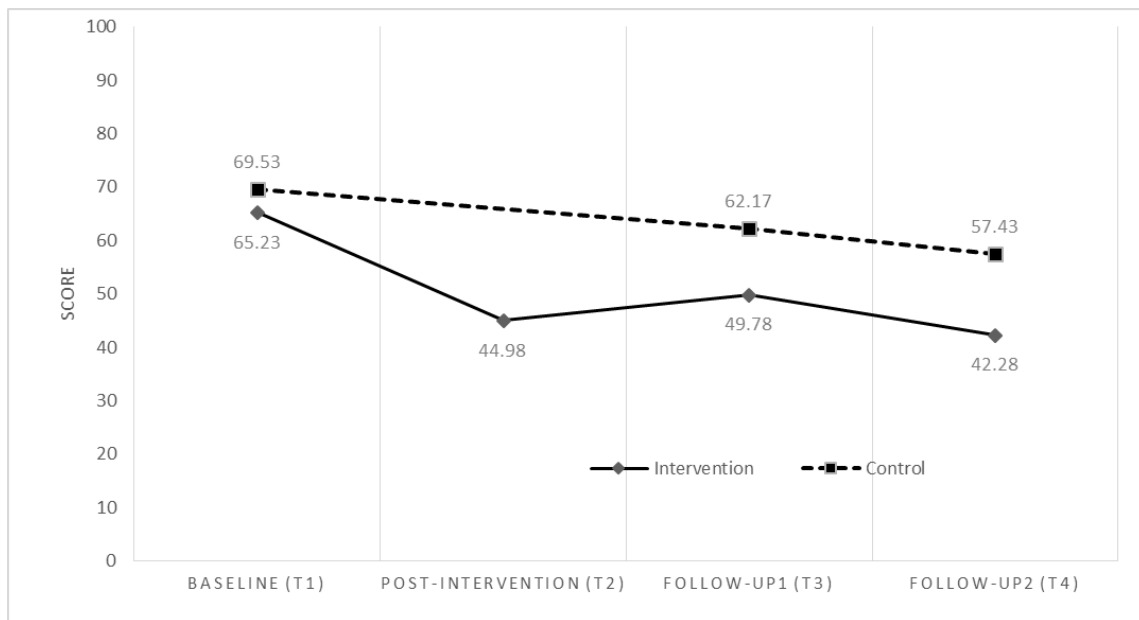
The baseline data did not indicate a significant difference between the groups (see Table 10). The mean score in the intervention group dropped by 15.45 from T1 to T3. The score at T3 between



the intervention group ( $49.78 \pm 17.9$ ) and the control group ( $62.17 \pm 26.15$ ) showed a significant difference ( $p = .02$ ). The difficulty level showed a gradual decrease down to T4 in both groups ( $42.26 \pm 19.93$  [intervention group],  $57.43 \pm 22.26$  [control group]) and the between-group difference remained at a significant level at T4 ( $p < .001$ ).

The two-way repeated measures ANOVA did not show a significant interaction between intervention and change over time ( $F(1.79, 135.76) = 2.84, p = .07$ ).

**Figure 3. Comparison of midwives' mean score for difficulties T1 through T4**



**Table 10. Comparison of midwives' frequency, difficulties and knowledge test scores T1 through T4**

	Intervention		Control		Mean difference between two groups							
	M	SD	M	SD	t	df	p <sup>e</sup>	difference	standard error	95%CI		
<b>Frequency</b>												
Baseline (T1 <sup>a</sup> )	8.59	0.87	8.51	0.91	0.38	82	.70	0.07	0.19	-0.31	0.46	
Follow-up1 (T3 <sup>b</sup> )	8.93	1.57	8.63	1.02	1.05	83	.30	0.30	0.29	-0.27	0.87	
Follow-up2 (T4 <sup>c</sup> )	8.83	1.21	8.63	1.07	0.83	83	.41	0.21	0.25	-0.29	0.70	
<b>Difficulties - VAS</b>												
Baseline (T1)	65.23	23.86	69.53	26.74	-0.75	76	.46	-4.30	5.73	-15.72	7.11	
Post-intervention (T2 <sup>d</sup> )	44.98	23.71	-	-								
Follow-up1 (T3)	49.78	17.90	62.17	26.15	-2.49	70.9	.02	-12.40	4.97	-22.31	-2.49	
Follow-up2 (T4)	42.28	19.93	57.43	22.26	-3.24	80	< .001	-15.15	4.67	-24.45	-5.85	
<b>Knowledge test</b>												
Baseline (T1)	7.12	3.35	7.35	3.53	-0.30	77	.77	-0.23	0.77	-1.77	1.31	
Post-intervention (T2)	16.07	3.33	-	-								
Follow-up1 (T3)	12.57	4.1	10.16	3.7	2.84	83	.01	2.41	0.85	0.72	4.09	
Follow-up2 (T4)	12.55	4.71	10.26	4.3	2.34	83	.02	2.29	0.98	0.35	4.24	

<sup>a</sup> T1: Prior to the intervention

<sup>b</sup> T3: One month after the intervention

<sup>c</sup> T4: Two month after the intervention

<sup>d</sup> T2: Immediate after the intervention (available only for the intervention group)

<sup>e</sup> p value of student's t-test

*Difficulties in five topics of promoting activities.*

The mean scores of each of the five topics at baseline did not show a significant difference between two groups.

Table 11 shows the difference of the level of difficulties in providing the information about five topics between the groups in two periods of time (T1 and T3, T1 and T4). The mean score differences of T1-T3 between the two groups was significant at four out of five topics (identifying age appropriate vaccines [ $p = .03$ ], scheduling for vaccination [ $p < .001$ ], explanation for herd immunity [ $p = .03$ ], and providing information about adverse events [ $p = .02$ ]). The intervention group showed a larger reduction in all five topics from T1 to T3. Nevertheless, the between-group difference was small and not significant at T4 in all topics (see Table 11 ). The difference of T1-T4 in the intervention group was larger than T1-T3, but the control group scores showed a greater improvement in T1-T4. This made the gap between the groups small at T4.

Of five topics, the highest mean score (which meant the midwives felt the most difficulty in mentioning) was prominently marked at “scheduling for vaccination” at consistently from T1 through T4 in both groups.

**Table 11. Midwives’ score difference in difficulties for five main topics between T1 and T3/T4**

Topics		Intervention (mean $\pm$ SD)	Control (mean $\pm$ SD)	p <sup>a</sup>
T1-T3	Age appropriate vaccines	-0.79 $\pm$ 1.02	-0.26 $\pm$ 1.18	.03
	Voluntary vaccines	-0.88 $\pm$ 1.35	-0.72 $\pm$ 1.40	.59
	Vaccination schedule	-0.93 $\pm$ 0.97	-0.09 $\pm$ 1.17	<.001
	Herd immunity	-1.36 $\pm$ 1.36	-0.70 $\pm$ 1.37	.03
	Adverse event	-0.83 $\pm$ 1.23	-0.26 $\pm$ 1.09	.02
T1-T4	Age appropriate vaccines	-0.79 $\pm$ 0.98	-0.53 $\pm$ 1.10	.27
	Voluntary vaccines	-1.00 $\pm$ 1.25	-0.93 $\pm$ 1.20	.79
	Vaccination schedule	-0.95 $\pm$ 1.01	-0.53 $\pm$ 1.01	.06
	Herd immunity	-1.48 $\pm$ 1.23	-1.07 $\pm$ 1.26	.14
	Adverse event	-1.05 $\pm$ 1.29	-0.65 $\pm$ 1.11	.13

<sup>a</sup> p-value of student’s t-test

***Perception of immunization and willingness for promoting activities.***

The mean scores of each of six items at baseline did not show a significant difference between two groups.

Table 12 shows the difference of perceptions and willingness between two groups in two periods of time (T1 and T3, T1 and T4). The mean score differences of T1-T3 between two groups were significant for two out of six items, namely “I do not have enough knowledge on immunization” ( $p < .001$ ) and “I have no up-dated information on immunization” ( $p = .03$ ). This indicates that the intervention group midwives had significantly reduced their negative perceptions of lack of knowledge and information one month after the intervention, compared with the control group. The difference between the two groups remained at a significant level at T4 in these two items (lack of knowledge [ $p = .01$ ], no up-dated information [ $p < .001$ ]) (see Table 12).

The perceptions of “lack of knowledge” and “no up-dated information” were the two lowest scoring items (which means the midwives had a strong agreement for those two items) from T1 through T4 in both groups. The perception of “I do not have time for immunization-promoting activities” remained about the same from T1 to T4 with around a 2.5 mean score in both groups.

Little change was shown in the items of “natural infection is better than vaccination”, “children should have all age appropriate vaccines (reversed scored item)”, and “I would like to recommend vaccination to my clients (reversed scored item)”. The possible reason for the minimal change is that these three items received relatively high scores of more than 3.5 at baseline. This implies the midwives did not have strong negative perceptions or unwillingness about immunization and its promoting activities before the research begun, and thus the perceptions were not significantly changed by the intervention.

**Table 12. Midwives' score difference of perception and willingness between T1 and T3/T4**

	Perceptions and willingness	Intervention (mean $\pm$ SD)	Control (mean $\pm$ SD)	p <sup>b</sup>
T1-T3	Lack of knowledge on immunization	-0.78 $\pm$ 1.01	-0.09 $\pm$ 0.92	<.001
	Not up-dated immunization related information	-0.61 $\pm$ 0.97	-0.14 $\pm$ 0.91	.03
	No time for immunization-promoting activities	-0.24 $\pm$ 1.39	-0.16 $\pm$ 1.23	.78
	Natural infection is better than vaccination	-0.02 $\pm$ 0.85	-0.09 $\pm$ 1.19	.76
	Children should have all age appropriate vaccines <sup>a</sup>	-0.29 $\pm$ 0.78	-0.35 $\pm$ 0.78	.74
	Like to recommend vaccination to my clients <sup>a</sup>	-0.37 $\pm$ 0.58	-0.23 $\pm$ 0.78	.38
T1-T4	Lack of knowledge on immunization	-0.80 $\pm$ 0.90	-0.35 $\pm$ 0.72	.01
	Not up-dated immunization related information	-0.76 $\pm$ 1.02	-0.12 $\pm$ 0.70	<.001
	No time for immunization-promoting activities	-0.07 $\pm$ 1.08	-0.07 $\pm$ 1.08	.99
	Natural infection is better than vaccination	-0.10 $\pm$ 0.92	-0.14 $\pm$ 1.15	.85
	Children should have all age appropriate vaccines <sup>a</sup>	-0.46 $\pm$ 0.84	-0.40 $\pm$ 1.00	.74
	Like to recommend vaccination to my clients <sup>a</sup>	-0.37 $\pm$ 0.77	-0.28 $\pm$ 0.85	.63

<sup>a</sup> reversed scored item

<sup>b</sup> p-value of student's t-test

### ***Knowledge test.***

The change in the mean score on the knowledge test is shown in Table 10 and Figure 4. The baseline data did not indicate a significant difference between two groups (see Table 10). Fisher's exact test also did not show a significant difference in either group among the 20 items.

For the baseline data, there were five out of 20 items in which more than 50% of midwives in both groups answered correctly. These items were "rubella vaccine for breastfeeding women", "rubella susceptibility and MR vaccine", "peak season for rotavirus infection" "duration of protection by a course of HB vaccination", and "difference between adverse event and side effect". On the other hand, six items had less than 20% correct answers, namely, "necessary vaccination coverage for herd immunity", "cocoon strategy", "simultaneous administration of live vaccines", "target disease of Hib/PCV vaccines", "two types of rotavirus vaccine", and "voluntary vaccines in early childhood".

The mean score dramatically increased at 16.07  $\pm$  3.33 immediately after the intervention (T2) (see Figure 4). In fact, 13 out of 20 items had more than 80 % of correct answers.

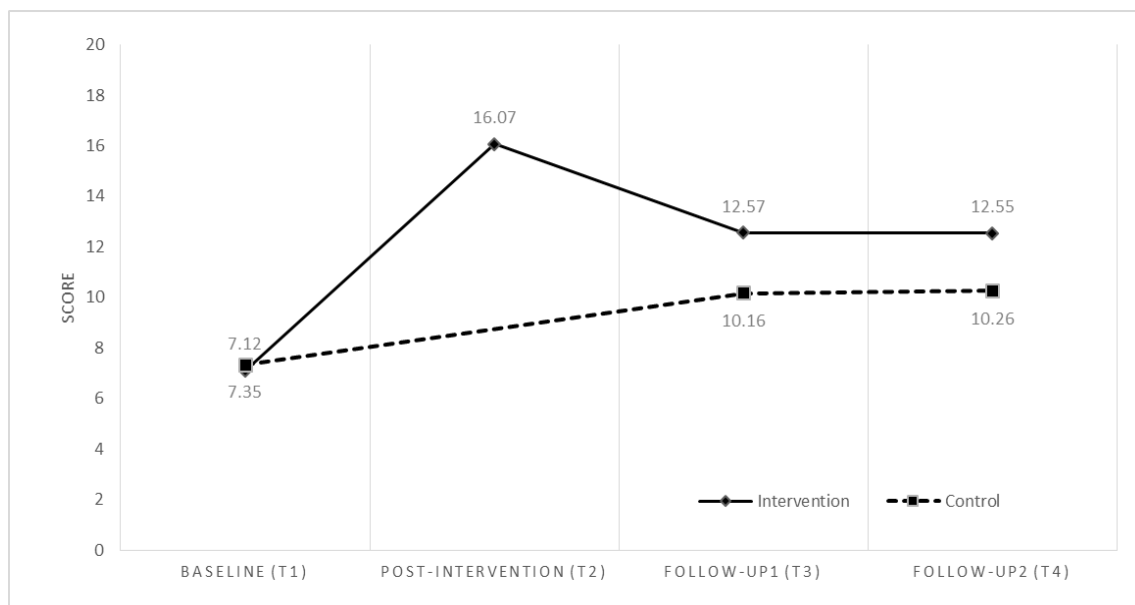
One month after the intervention (T3), the mean score remained at a significant level as 12.57  $\pm$  4.1 in the intervention group and 10.16  $\pm$  3.7 in the control group ( $p = .01$ ). Fisher's exact test showed a significant difference in five items between the groups, namely "cocoon strategy" ( $p = .02$ ), "timing of initial vaccination" ( $p = .01$ ), "two types of rotavirus vaccines" ( $p = .05$ ), "difference between adverse event and side effect ( $p = .01$ )" and "voluntary vaccines in early childhood" ( $p = .05$ ).

The percentage of correct answers was significantly higher among the intervention group midwives for these five items.

There had been a little change in the mean scores from T3 to T4 ( $12.55 \pm 4.71$  in the intervention group and  $10.26 \pm 1.3$  in the control group) and the between-group difference in mean scores remained at a significant level ( $p = .02$ ). The item of “voluntary vaccines in early childhood” showed a significant difference between the groups at T4 ( $p = .01$ ).

The two-way repeated measures ANOVA indicated a significant interaction between intervention and change over time ( $F(1.76, 132.82) = 4.91, p = .01$ ). The ANOVA did not show a significant main effect of intervention ( $F(1.76, 132.82) = 3.66, p = .06$ ) although the effect of change over time was a significant ( $F(1.76, 132.82) = 57.84, p < .001$ ). The result indicates that the difference of knowledge score between the intervention and the control groups could narrow as time advances.

**Figure 4. Midwives’ mean scores of knowledge test T1 through T4**



## Mothers

### Demographic characteristics.

As Figure 2 shows, 238 mothers responded to the questionnaire at the one-month checkup (123 in the intervention group facilities and 115 in the control group facilities). Of those, 95 (54 in the intervention facilities and 41 in the control group facilities) returned the postcard around a month after the questionnaire survey.

Table 13 shows the characteristics of the 238 participating mothers. There was no statistically significant difference between the two groups. The majority of respondents were aged 20s-30s (90% of the intervention group and 92% of the control group). About half of the respondents had one child (the relevant infant was their first child) (55% of the intervention group and 48% of the control group).

**Table 13. Demographic characteristics of mothers (N = 238)**

		Intervention n=123	Control n=115	p
Age (n, %)	< 20	1 ( 0.8)	1 ( 0.9)	.07 <sup>a</sup>
	20s	28 (22.8)	38 (33.0)	
	30s	82 (66.7)	68 (59.1)	
	≥40s	7 ( 5.7)	4 ( 3.5)	
	NA	5 ( 4.1)	4 ( 3.5)	
Number of children (n, %)	One	68 (55.3)	56 (48.7)	.54 <sup>b</sup>
	Two	40 (32.5)	43 (37.4)	
	Three or more	10 ( 8.1)	12 (10.4)	
	NA	5 ( 4.1)	4 ( 3.5)	
Academic background (n, %)	Junior/high school	24 (19.5)	26 (22.6)	.41 <sup>b</sup>
	Diploma	44 (35.8)	48 (41.7)	
	Bachelor or higher	49 (39.8)	37 (32.2)	
	NA	6 ( 4.9)	4 ( 3.5)	
Employment status (pre-pregnancy) (n, %)	Housewife	33 (26.8)	36 (31.3)	.40 <sup>b</sup>
	Part time worker	18 (14.6)	27 (23.5)	
	Full time worker	66 (53.7)	48 (41.7)	
	NA	6 ( 4.9)	4 ( 3.5)	

Note. NA=not available

<sup>a</sup> Mann-Whitney U test

<sup>b</sup>  $\chi^2$  test

### Primary outcome.

The primary outcome of mothers was their intention to have their infant vaccinated with two voluntary vaccines (HB and rotavirus infections).

Table 14 shows the maternal intention for six target vaccines for their infants at the time of the one-month checkup. The intention of permitting two voluntary vaccines in the intervention group mothers was significantly higher than those of the control group mothers ( $p < .001$  [HB vaccine],  $p < .001$  [Rotavirus vaccine]). In contrast, the between-group difference was not significant for the four routine vaccines.

**Table 14. Maternal intention for six target vaccines (N = 238)**

Vaccines	Intention	Intervention (n,%)	Control (n,%)	p
Hib <sup>a</sup>	Yes	108 (87.8)	97 (84.3)	.44 <sup>c</sup>
	No	15 (12.2)	18 (15.7)	
PCV <sup>a</sup>	Yes	110 (89.4)	96 (83.5)	.18 <sup>c</sup>
	No	13 (10.6)	19 (16.5)	
DPT-IPV <sup>a</sup>	Yes	121 (98.4)	112 (97.4)	.68 <sup>d</sup>
	No	2 (1.6)	3 (2.6)	
BCG <sup>a</sup>	Yes	118 (95.9)	110 (95.7)	1.00 <sup>d</sup>
	No	5 (4.1)	5 (4.3)	
HB <sup>b</sup>	Yes	77 (62.6)	44 (38.3)	< .001 <sup>c</sup>
	No	46 (37.4)	71 (61.7)	
Rotavirus <sup>b</sup>	Yes	88 (71.5)	55 (47.8)	< .001 <sup>c</sup>
	No	35 (28.5)	60 (52.2)	
Not determined	Yes	1 ( .8)	1 ( .9)	1.00 <sup>d</sup>
	No	122 (99.2)	114 (99.1)	

<sup>a</sup> Routine vaccine

<sup>b</sup> Voluntary vaccine

<sup>c</sup>  $\chi^2$  test

<sup>d</sup> Fisher's exact test



## Secondary outcome.

### *Timeliness of initial vaccination.*

The total response rate of postcard survey was 39.9 %. There was a 43.9% response from the intervention group and a 35.7% response from the control group.

Of the four initial vaccines, the intervention group showed significantly higher coverage in HB vaccine, compared with that of the control group ( $p < .001$  [Fisher's exact test]). There was no significant difference among the remaining three vaccines.

As Table 15 shows, the median number of days between the birth and initial vaccination day for the intervention group and the control group showed significant differences in all four initial vaccines. The timing of the initial vaccination was significantly earlier among the intervention group infants than that of the control group.

The prevalence of simultaneous vaccination of the four initial vaccines was significantly higher among the intervention group (55.6%) compared to the control group (17.1%) ( $p < .001$  [ $\chi^2$  test]).

**Table 15. Timing of initial vaccination for intervention and control group (N=95)**

Vaccines	Intervention (n=54)			Control (n=41)			z	p <sup>a</sup>
	n (%)	median	IQR	n (%)	median	IQR		
Hib	52 (96.3)	62	6	38 (92.7)	67	10	-3.07	.002
PCV	51 (94.4)	62	6	38 (92.7)	68	11	-3.33	.001
HB	36 (66.7)	62	5	13 (31.7)	68	29	-2.80	.01
Rotavirus	37 (68.5)	62	6	21 (51.2)	68	12	-2.93	.003

Note. IQR=interquartile range

<sup>a</sup> p-value of Mann-Whitney U test

### *Rubella susceptibility and vaccination.*

There was no significant difference between the groups in the mothers' recognition of rubella susceptibility and the need for rubella vaccination.

Only 12% of the intervention group and nine % of the control group mothers responded that they did not know their immunity against rubella. The rest of mothers recognized their susceptibility. Among the mothers who knew their susceptibility, 50% of the intervention group and 48% of the control group were not susceptible based on the antibody testing in the pregnancy. Some mothers (7% of the intervention group and 2% of the control group) already had rubella vaccination in the current

postpartum period.

Of those susceptible to rubella, six % of the intervention group and 11% of the control group planned to become vaccinated in the days ahead, but 24% of the intervention group and 30% of the control group were uncertain whether or not they would get vaccinated.

#### ***Preparatory action.***

There was no significant difference between the groups in terms of the progress of the health facility selection for initial vaccination. More than 70% of mothers in both groups had already taken a preparatory action (either “made an appointment”, “selected a facility”, or “started looking for facilities”). Of those mothers taking action, 57% of the intervention group and 61% of the control group had accomplished the facility selection at the time of the one-month checkup, but only three % of the intervention group and four % of the control group completed a booking.

On the other hand, 27% of the intervention group and 22% of the control group mothers responded that they had not started looking for the facility yet.

#### ***Knowledge test.***

The knowledge test score did not show a significant difference between the groups either in the total mean score or in each of the ten items.

The mean scores of the intervention and control groups were  $3.73 \pm 2.73$  and  $3.55 \pm 2.85$ , respectively.

Two items asking about “the route of transmission for tetanus” and “symptoms of rotavirus infection” had higher percentages of right answers with more than 50% of mothers in both groups responding correctly. On the other hand, the lowest percentage of right answers was found for two items: “prognosis of HB infection in early childhood” and “combination of DPT-IPV vaccine”. Fewer than 20% of mothers answered those items correctly.

#### ***Recognition of immunization-promoting activities by midwives.***

Of the five occasions when mothers could possibly have received immunization-promoting activities from midwives, the highest number was shown at the postpartum admission period at IPD in both groups (see Table 15). The number of mothers who received the promoting activities in that

particular period was significantly higher among the intervention group mothers ( $p < .001$ ). The rest of the occasions did not show a significant difference between the groups.

**Table 16. Maternal recognition of immunization-promoting activities by midwives**

Possible occasions	Received	Intervention (n, %)	Control (n, %)	p
Childbirth class in prenatal period	Yes	13 (10.6)	11 (9.6)	.80 <sup>a</sup>
	No	110 (89.4)	104 (90.4)	
Prenatal checkup at OPD	Yes	13 (10.6)	12 (10.4)	.97 <sup>a</sup>
	No	110 (89.4)	103 (89.6)	
Prenatal admission to IPD	Yes	3 (2.4)	2 (1.7)	1.00 <sup>b</sup>
	No	120 (97.6)	113 (98.3)	
Postpartum admission to IPD	Yes	71 (57.7)	25 (21.7)	< .001 <sup>a</sup>
	No	52 (42.3)	90 (78.3)	
Postpartum breastfeeding consultation	Yes	8 (6.5)	10 (8.7)	.52 <sup>a</sup>
	No	115 (93.5)	105 (91.3)	

*Note.* OPD=Outpatient department; IPD= Inpatient department

<sup>a</sup>  $\chi^2$  test

<sup>b</sup> Fisher's exact test

## Program evaluation

### *Reaction of participants*

The final questionnaire, for both groups of midwives, at two months, included three questions about their awareness and self-learning behavior. The results indicated that the majority of the participants had looked through the distributed handbook (82% in the intervention group and 93% in the control group) but only few of them accessed one of the web-site address on the list (8% in the intervention group and the 18% in the control group). The level of interest about immunizations was increased after participating in the research for 80% of the intervention group midwives and 93% of the control group midwives. Fisher's exact test did not show a significant difference between groups for any of the three items.

Both groups were told they could ask the researcher any question through e-mail or face-to-face during the research period. The researcher received an e-mail and a face-to-face question from the intervention group midwives. These questions were about a tetanus vaccine for travel for pregnant women and post-exposure management against varicella for women in labor. No inquiry was made by the control group midwives.

### *Evaluation of the lecture*

The post-intervention questionnaire, which only the intervention group midwives filled out immediate after receiving the lecture, included the six questions for their reaction. Table 16 shows the mean values and the standard deviation of their ratings with a five-point Likert scale of one (*strongly disagree*) to five (*strongly agree*).

In general, the participants assessed the program relatively high as the means of four out of six items were above four points (see Table 16). While the length of the lecture was rather short at around one hour, the relatively low mean score indicates that some participants did not feel it was short. To present themselves soon after work might have been a burden for some of the participants.

**Table17. Reaction of participants** n = 41 (not available = 1)

	m (SD)
Facilitator explained clearly	4.37 (0.62)
Content was easily comprehensible	4.34 (0.62)
Content was practical for daily work	4.27 (0.63)
Program was recommendable for others	4.24 (0.77)
Content met participants' needs	3.90 (0.62)
Length was too short	2.56 (0.90)

The feedback left by the participants in the comment column were as follows: “It was a good opportunity for reviewing immunization matters”, “I was able to learn a lots of things about immunization”, “I realized the importance of vaccination, “It was good to be able to up-date the related information”, and some senior midwives noted “the latest information was quite different what I learned in the past”.

### *Fidelity monitoring*

In order to determine the extent to which the educational program was carried out as planned, the fidelity monitoring was done using a third person observational method. Using the checklist (Appendix 15), five observers checked eight out of 14 lectures. The five researchers in the fields of midwifery and nursing were involved in the fidelity monitoring as rater. The researcher provided a briefing session to describe the detail of monitoring for each rater prior to the involvement.

The lectures were given full score in all aspects (five points in five aspects) except for the first one. The first lecture was marked down one point for “exposure” and two points for “program differentiation”. The reasons for the lowered marks were (1) the start time was delayed due to the difficulty of venue arrangement, and (2) some participants left in the middle of the lecture to attend to an emergency C-section.

## **Discussion**

### **Midwives’ outcome**

The present study demonstrated to what extent the brief educational session was effective in increasing the midwives’ knowledge, and how this affected their perceptions and could lead to their change in practice. The findings showed the intervention was effective in increasing participants’ knowledge and in reducing their feelings of difficulty in providing immunization-promoting activities. The self-reported indicator of midwives’ behavioral change, the frequency of immunization-promoting activities, did not result in a significant increase after the intervention, though a positive effect was seen.

While more than several studies outside Japan examined the effect of provider education, the target of these studies were healthcare providers directly involved in vaccination practice (Boom, Nelson, Kohrt, & Kozinetz, 2010; Franzini, Boom, & Nelson, 2007; Hayney & Bartell, 2005; Levi, 2007; Margolis et al., 2004; Taylor et al., 2008; Uskun et al., 2008). Basically, the midwives in Japan are not vaccination-provider practitioners but they are in position to provide the immunization-related information for women and their families during perinatal period. The educational program in the present study aimed at enabling them to fulfill their role as information providers.

### *Knowledge.*

The participants’ knowledge was improved after attending the program and remained high for two months of the post-intervention period with the significant between-group difference. The positive results in knowledge acquisition were observed in some previous studies using the before-after design (Levi, 2007; Uskun et al., 2008; Zimmerman et al., 1997). All of them assessed the change in professional knowledge with pre/post-test questionnaires immediate before and after the intervention, but none of the studies demonstrated change over time.

In the present study, the intervention group midwives recognized that they had acquired knowledge and up-dated information after attending the program. The between-group score differences of these two perceptions (knowledge and information) remained at significant level for two months after the intervention. The one hour lecture program in the present study can be adequate to increase the participants' knowledge and to retain it for about two month, yet how much longer the acquired knowledge can be maintained and how frequently the subsequent training is required in this particular population remains to be solved.

#### *Feelings of difficulty.*

The feeling of inadequate knowledge was assumed to be the biggest obstacle for midwives to provide immunization-promoting activities. Thus once the participants acquired knowledge, their feelings of difficulty for immunization-promoting activities was reduced. In fact, the feelings of difficulty VAS score in both groups continued to decrease over the two months. The significant between-group difference indicated that the amount of obtained knowledge determines the extent of reduction of feelings difficulty.

No provider education study was found which included the participants' feelings difficulty in the intervention outcome. Instead of feelings of difficulty, some before-after studies with other subjects, such as the provider education for breast cancer screening and breastfeeding (Bryan, Estrada, Castiglioni, & Snyder, 2015; Mellin, Poplawski, Gole, & Mass, 2011), used "comfort level" as an outcome indicator. The results showed a significant improvement in the comfort level of the participants in discussing and counseling the subject matters with their clients. The increased comfort level among the healthcare providers led to the change in their practice or the positive feedback from their clients in these studies.

#### *Frequency of promoting activities.*

The considerable reduction in feelings of difficulty was not correlated with an increase in participants' providing immunization-promoting activities in the present study. The midwives in both groups reported that they seldom or never provided health guidance on immunization to their clients before the study began, and the frequency was not significantly changed after the program. As a mentionable post-intervention effect, the intervention group facilitated distributing a flyer as an

information delivery medium. The decision of flyer distribution was made in the staff meeting and the pediatric department was also involved in checking the content prior to the distribution in each facility.

Practically, the flyer was distributed as part of a handout package, and the distributor was not always a midwife but other health care providers such as the ward pharmacist. Consequently, with the absence of verbal instruction, many of the midwives felt they did not actually provide the immunization-promoting activities to their clients, and this could be the reason for not reflecting the behavioral change in the follow-up questionnaires.

The increased awareness midwives achieved by attending the program possibly facilitated the acceptability of flyer distribution at the intervention group hospitals. Familiarizing the participants with immunization issues might have made them ready to respond client enquires. The organizational commitment would not be made without the positive attitude of the participants towards the subject matter.

A few previous studies included the healthcare providers' behavioral change in their evaluation (Boom et al., 2007; Taylor et al., 2008). As these studies were targeted at vaccination practitioners, the participants' behavioral change meant the procedure of vaccination practice rather than information provision. No study conducted in industrialized countries focused on the change in practice of information provider.

#### *Maternal response to midwives' change in practice.*

The previously cited study of breastfeeding (Mellin et al., 2011) assessed the healthcare providers' behavioral change (% of active observation) with the beneficiary survey of mothers. The mothers reported an increase in the staff observation after the provider education.

The present study compared the midwives' self-reported data of providing immunization-promoting activities with their clients' recognition of receiving immunization-promoting activities. Contrary to the midwives' report, the questionnaire survey of mothers showed that a significant number of the intervention group mothers responded that they were provided the immunization-related information from the midwives in their postpartum admission period.

There were several possible reasons for the discrepancy between the midwives' and the mothers' perceptions about immunization-related information provision: (a) One possible reason was the effect of the above mentioned flyer distribution. In responding to the questionnaire, the mothers might have

recalled the flyer they received and assumed the distributors were all midwives. (b) Another reason might be the underreporting of midwives. The midwives were told to report any kind of promoting activities done in the past week irrespective of its content and amount, but the minor activities without oral explanation might not have been taken into account in the report.

### **Maternal outcome**

The present study showed the practical effect of information provision derived from the provider education with the maternal intention and the initial vaccination uptake.

As the immunization uptake is the end-user outcome for the provider education, several studies attempted to demonstrate the impact of the intervention with client immunization uptake (Boom, et al., 2010; Franzini, et al., 2007; Margolis, et al., 2004; Taylor, et al., 2008; Watermen, et al., 1996). Nevertheless, only two before-after studies conducted in the US and Turkey yielded positive results (Hayney & Bartell, 2005; Uskun, et al., 2008). The present study suggested the possible impact of provider education on maternal intention with a control study design, and implied the effect may extend to actual immunization uptake.

#### *Maternal intention and initial vaccination status.*

The maternal intention for two voluntary vaccines was significantly higher in the intervention group at the time of one-month checkup. In comparison with the available data of immunization uptake, the intention of rotavirus vaccination among the intervention group mothers was higher (71.5%) than the estimate of national average (45%) (Ministry of Health, Labour and Welfare, Japan, 2013b), and was similar to the preliminary study (73.4%) (Endo, 2014). HB vaccination showed a higher intention (62.6%), compared with the preliminary study (28.2%) (Endo, 2014).

The maternal intention for Rotavirus vaccine was higher than HB vaccine in both groups as with the preliminary study result. The possible reason for this is the difference of parental knowledge about the diseases. Compared to Rotavirus infections associated with seasonal epidemic, HB infection is not a “close-to-home” disease for most parents in Japan. The knowledge test results of the present study and the preliminary study both showed the risk of HB infection for infants is not well recognized among mothers (Endo, 2014). Healthcare providers in hospitals and local governments need to make further efforts to disseminate sufficient information about HB vaccine to create the positive parental



intention.

The postcard survey at two months, though the response rate was fairly low, supported the positive maternal intention of the intervention group by showing the high vaccination rate of HB vaccine and the timeliness of initial vaccinations. The result of the timing of initial vaccination suggested that the simultaneous administration of voluntary vaccines was commonly practiced among the intervention group.

The preliminary study indicated that the number of initial vaccines is affected by the information that mothers hold (Endo, 2014). One of the possible reasons for the positive intention among the intervention group mothers can be due to the provision of information in the study hospitals. While mothers with infants obtain immunization-related information from various sources such as the local administration office and through the Internet, the hospital where they gave birth was one of the information centers (Endo, 2014). The intervention group facilities delivered the message encouraging timely and full-range of initial vaccination through the flyer, and this additional input possibly influenced creating the positive maternal intention.

#### *Rubella susceptibility.*

The between-group difference was not detected in the rubella-related question. A minority, 35% of the respondents were susceptible to rubella and the majority of them (76%) did not have a plan to vaccinate in the future. All participants were supposed to have rubella antibody testing during pregnancy, but around 10% of mothers did not know their susceptibility at one month after childbirth.

The perinatal period is thought to be a favorable opportunity for providing the related information since clients' have increased awareness towards their health including protection against infectious diseases (Návar, Halsey, Carter, Montgomery, & Salmon, 2007; Saitoh et al., 2013; Zola, Smith, Goldman, & Woodruff, 1997). Considering the recent 2012-2013 epidemic of rubella in Japan (Ujiie et al., 2014), healthcare providers need to pay more attention to those susceptible population (women and men ) in the reproductive age group and should minimize the missed opportunity to promote their preventive action. Only a participating facility offered rubella vaccination for postpartum women during the admission period at IPD, thus increased efforts to improve the accessibility of rubella vaccination for mothers are necessary.

### *Preparatory action.*

The between-group difference was not detected in the progress of facility selection. A minority, 24% of the respondents did not take preparatory action at the time of one-month checkup.

According to the preliminary study, the necessary preparation period for initial vaccination was suggested as one month (Endo, 2014). Mothers who started the information collection after one-month checkup tended to not complete the full-range of vaccination for their infant. Thus, the 24% of population with non-preparatory action in the present study might be at the risk for missing opportunity to initial vaccination.

For most of mothers, the one-month checkup is the last perinatal visit to the hospital where they gave birth (the next checkup is around four month at local health centers in Japan). Thus, hospital healthcare providers are responsible for ensuring the preparedness of parents for their life in the next couple of months including the initial vaccinations and providing necessary advice to reduce the risk of missing future immunization opportunities.

### *Knowledge.*

Compared with Endo's (2014) preliminary study, the mean score of the present study ( $3.64 \pm 2.78$ ) was lower than the preliminary study population ( $5.71 \pm 2.34$ ). The percentage of right answer was also lower in all questions. Among ten questions including in the questionnaire, only two (route of transmission for tetanus and symptoms of rotavirus infection) showed more than 50% of the respondents answering correctly. The lowest two questions were the same as the preliminary study (prognosis of HB infection in early childhood and combination of DPT-IPV vaccine) as fewer than 20% of mothers had the right answer. The score confirmed that HB vaccine is lesser of the known vaccines for mothers with regards to the two voluntary vaccines (Hori, 2014).

### **Implications for information provision in perinatal period**

The postpartum women in Japan usually maintain the relation to their delivery hospital until at least one month after childbirth. Through the antenatal visits and the admission for delivery, obstetric healthcare providers can be the largest information source for women during the perinatal period. Compared with pediatric care providers, obstetric providers are thought to be less aware of their role as information providers about immunizations (Link-Gelles et al., 2012; Návar et al., 2007). The US

national survey of obstetricians indicated that the obstetric providers underestimate their influence with their pregnant clients' decisions to vaccinate their future children, although they are recognized to be the most trusted healthcare providers for pregnant women (Link-Gelles et al., 2012).

The optimal timing for providing immunization-related information for parents has not been established (Briss et al., 2000; Williams et al., 2011), but the previous studies suggested the importance of information provision during the perinatal period (Návar et al., 2007; Saitoh et al., 2013; Wroe, Turner, & Salkovskis, 2004). Wore et al. (2005) claimed that the parental intention during pregnancy was the strong predictor for their infants' actual uptake. The obstetric providers have the unique potential to facilitate pregnant women's positive intention for vaccinations (Link-Gelles et al., 2012), and the same possibly also holds for midwives in Japan. Thus the in-service training which enables obstetric providers to fulfill their role as immunization information provider is necessary in order to minimize the missed opportunity for their clients.

### **Limitations**

Considering the complexity of the immunization issues, attributing the positive maternal outcome merely to the educational intervention is difficult (Ellis, Roland, & Blair, 2013). If the program participants are not directly involved in vaccination practice, establishing the linkage between the provider education and their clients' vaccination outcome becomes more complex. Thus the results yielded in the present study should be interpreted with the following limitations.

There were several parameters, which could not be controlled with the non-randomized study design and might have affected the outcome such as the socio economic status of parents, the accessibility of health facilities, the difference in immunization practice of local health facilities, and advice from other health care providers where parents resided. Moreover, the facility-based allocation with a convenience sampling cannot avoid attributional differences of each hospital including the regional characteristics, and this possibly affected the maternal findings.

### **Suggestions for future research**

The educational program in the present study requires further improvement in terms of the content and the means of implementation. As the program did not include communication skill practice, those who were not skilled in discussing immunization issues may not have been able to envision the

actual dialogue with their clients. Showing some model practices according to the common encounters at OPD and IPD might be helpful for visualizing the practical approach of information delivery. Considering the efficacy of the educational program, the lecture style program is limited in its practicality with requiring manpower. An e-learning educational program focused on in-service midwives needs to be developed with incorporating the lessons from the present study.

The future program should include the perspective of evaluation in the development process. As Ellis et al. (2013) suggested, the evaluation would be recommended to conduct with RCT design, ideally using a large sample population with cluster sampling in order to control the influencing parameters. The long-term effect of educational program also needs to be followed. An effort should be made to trace the indicator of ultimate outcome, namely, the action taken by mothers and/or the actual vaccination status of their infants.

## Conclusion

The effectiveness of an in-service educational program about immunization for midwives was examined with 81 participants by using longitudinal control study design. The intervention effect was also evaluated with the 238 of mothers with infants. The following is the summary of findings.

### *Midwives*

1. The primary outcome of the frequency of providing immunization-promoting activities by midwives did not show a significant increase after the intervention.
2. The difficulty in providing immunization-promoting activities was significantly eased by acquiring the knowledge.
3. The perception of “lack of knowledge” and “no up-dated information” were significantly decreased after the intervention.
4. The knowledge level increased by the intervention and remained at significant level for two months.

### *Mothers*

1. The maternal intention for two voluntary vaccines (HB and rotavirus infections) for their infants was significantly higher among the mothers of the intervention group facilities.
2. Timely vaccination along with the simultaneous administration of four initial vaccines was significantly common among the infants of the intervention group facilities.
3. The maternal recognition of being provided immunization-related information from their midwives was significantly higher among the mothers of the intervention group facilities.

The didactic in-service educational program for midwives was effective in increasing the knowledge and decreasing the feelings of difficulty in information provision. The impact on clients was found in the creation of a positive maternal intention to vaccinate their infants, and the favorable coverage of timely initial vaccination with simultaneous administration.

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