



Effect of stepwise perinatal immunization education: A cluster-randomized controlled trial



Aya Saitoh ^{a,*}, Akihiko Saitoh ^b, Isamu Sato ^c, Tomohiro Shinozaki ^d, Hajime Kamiya ^e, Satoko Nagata ^a

^a Department of Community Health Nursing, Division of Health Sciences and Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

^b Department of Pediatrics, Niigata University Graduate School of Medical and Dental Sciences, Niigata, Japan

^c Yoiko-no Shounika Sato, Niigata, Japan

^d Department of Biostatistics, School of Public Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

^e Infectious Disease Surveillance Center, National Institute of Infectious Diseases, Tokyo, Japan

ARTICLE INFO

Article history:

Received 27 October 2016

Received in revised form 20 January 2017

Accepted 27 January 2017

Available online 17 February 2017

Keywords:

Perinatal immunization education
Infant immunization status
Maternal immunization knowledge
Cluster-randomized controlled trial

ABSTRACT

Background: Perinatal immunization education is important for improving the immunization outcomes of infants; however, the content of educational materials used at each perinatal period has not been carefully evaluated. We hypothesized that stepwise education offered at different perinatal periods would improve infant immunization status and enhance maternal immunization knowledge.

Methods: In this cluster-randomized controlled trial, pregnant women were recruited from nine obstetric sites in Niigata, Japan. The intervention group received a stepwise, interactive education intervention (prenatally, postnatally, and 1 month after birth). The control group received a leaflet containing general information on immunization. Infant immunization status was evaluated at 6 months of age, and maternal immunization knowledge was evaluated by a written survey after each intervention.

Results: Among 188 study participants, 151 (80.3%) replied to the final post-intervention survey. At 6 months of age, the percentage of children who completed three doses of inactivated polio, diphtheria, tetanus toxoid, and acellular pertussis (DTaP-IPV) vaccine was higher in the intervention group than in the control ($p = 0.04$); however, no differences between groups were observed for the *Haemophilus influenzae* type b (Hib) ($p = 0.67$) or 13-valent pneumococcal conjugate (PCV13) vaccines ($p = 0.20$). The duration to the completion of the third dose of the DTaP-IPV, Hib, and PCV13 vaccines was shorter in the intervention group than in the control ($p = 0.03$, $p < 0.01$, and $p < 0.01$, respectively). Furthermore, maternal knowledge scores exhibited significantly greater improvement in the intervention group over time compared with those of the control group ($p = 0.02$).

Conclusions: Stepwise perinatal immunization education improved immunization schedule adherence for required vaccines and improved maternal immunization knowledge.

© 2017 Elsevier Ltd. All rights reserved.

1. Introduction

Some educational interventions improve immunization coverage or intention to vaccinate. The success of immunization programs depends on parents having sufficient information [1,2].

Abbreviations: HCPs, healthcare providers; VPDs, vaccine-preventable diseases; PCV13, 13-valent pneumococcal conjugate vaccine; Hib, *Haemophilus influenzae* type b; HBV, hepatitis B virus; DTaP, IPV-diphtheria, tetanus toxoid, acellular pertussis, and inactivated polio virus vaccine; ITT, intention to treat; HBM, Health Belief Model.

* Corresponding author at: Division of International Health, Graduate School of Medical and Dental Sciences Niigata University, 1-757 Asahi-machi-dori Chuo-ku, Niigata 951-8510, Japan.

E-mail address: aya-saitoh@umin.ac.jp (A. Saitoh).

Many high-income countries provide standardized immunization education. In the United States, instruction regarding infant immunization is routinely provided, with healthcare providers (HCPs) being legally required to communicate the risks/benefits of vaccines such as necessity of immunization, side effects, and contraindications; however, information is often insufficient and depends on HCP initiative [3–6].

In Japan, approximately one-third of vaccines are voluntary [7]. Information is particularly limited for these vaccines and accordingly they are perceived as less important than required vaccines [8]. Furthermore, out-of-pocket fees for vaccines limit vaccination rates. The estimated vaccination rates for voluntary vaccines, such as mumps, rotavirus, and influenza vaccines, are 30%, 45%, and 40%, respectively [9]. In addition, with a limited use of combination

vaccines, simultaneous vaccination is not widely accepted owing to questions regarding its safety [7,10].

Effective educational interventions should be provided early [11–15]. A delay in the first vaccination may impact adherence to the immunization schedule and increase the risk of vaccine-preventable diseases (VPDs). Perinatal educational interventions are effective [12,15–17]; they increase knowledge and improve immunization status [14,18]. However, the effect of stepwise education at different perinatal periods on infant immunization status and maternal knowledge is unknown.

Information preferences differ before and after childbirth. Prior to giving birth, women desire general information, such as definitions of immunization, VPD characteristics, and vaccine types. After giving birth, women want detailed information regarding the timing and method of vaccine administration. The theory of the teachable moment [19,20], in which natural health events motivate individuals to adopt risk-reducing behaviors, suggests that interest in immunization information changes over time [19,20]. Therefore, educational interventions must target the needs of pre- and postnatal populations [19,21], and this may improve adherence to immunization schedules [21].

This study investigated the impact of a stepwise immunization education intervention on infant immunization status and maternal knowledge compared to a control group.

2. Patients and methods

2.1. Study design and setting

This was a pair-matched, cluster-randomized, controlled trial conducted in obstetric hospitals and clinics in Niigata, Japan. Participating institutions were Niigata University Hospital, four affiliated hospitals, and four private obstetric clinics. The annual number of deliveries at these sites ranged from 100 to 800.

2.2. Eligibility and enrollment

Pregnant women aged ≥ 18 years and able to communicate in Japanese were recruited by a midwife or physician during gestational weeks 24–30 at antenatal classes or prenatal checkups at each site from September 15, 2014 to January 31, 2015. Demographic information included employment status, education, infant date of birth, number of children, and family structure.

Cluster-randomization was used for practical reasons and to prevent contamination by participant and physician preferences. First, the clusters were stratified by either hospital or clinic. Each cluster, including two or three hospitals or clinics, was divided into two groups, and they were randomized between the intervention and control groups. A third-party researcher used computer-generated random numbers to allocate medical centers to each of the four pairs of intervention and control groups. Because the intervention was an educational program, blinding the study staff and participants was not possible.

2.3. Sample size

Sample size was determined using vaccination completion rate, i.e., proportion of infants vaccinated with *Haemophilus influenzae* type b (Hib), 13-valent Pneumococcal conjugate (PCV13), diphtheria, tetanus toxoid, acellular pertussis, and inactivated poliovirus (DTaP-IPV), hepatitis B virus (HBV), and rotavirus, as the primary outcome. A 10% completion rate was assumed for the control group [18]. Therefore, 37 subjects in each treatment group was sufficient to detect a completion rate of 40% in the intervention group with a power of 80% at a significance level of $p = 0.05$ using a two-sided

t-test. An estimated intracluster correlation of 0.05 (giving a design effect of 1.95 based on an average of 20 participants per cluster) requires a sample size of 160 parents (80 in each treatment group). Assuming an attrition rate of 25%, each treatment group required 108 parents.

2.4. Ethical considerations

This study was approved by the Institutional Review Boards of the University of Tokyo (#10384), Niigata University Hospital (#1882), and Saiseikai-Niigata-Daini Hospital (#E14-02).

2.5. Intervention

Prior to delivering educational interventions, educators at each participating site were provided with the study protocol and guidance on intervention delivery. Immunization education was provided to participants in the intervention group in three one-on-one interactive sessions: during the prenatal period (34–36 gestational weeks) in an outpatient setting, during the postpartum period (3–6 days after delivery) in an inpatient ward, and at the 1-month well baby checkup in an outpatient setting. Educators covered subjects focused on the immunization content of greatest interest to mothers at each perinatal stage. All education sessions were implemented using a booklet containing all relevant information, as determined by Japanese immunization specialists [21], and included the infant immunization schedule issued by the Japan Pediatric Society [22]. Each session lasted approximately 5 min.

The control group received an educational pamphlet without an oral explanation. The pamphlet covered a wide range of subjects related to immunization, which included all of the same topics as the intervention group, and was designed as a supplement to general immunization information provided at routine check-up visits. They received the pamphlet at routine check-up during the perinatal period (34–36 gestational weeks).

2.5.1. Educational program content

The content of the education program is shown in Table 1. The program was developed by the authors based on the results of a pilot study [21]. In the pilot study, 10 items addressing immunization information (Supplementary Table 1) for caregivers, such as VPDs, immunization schedules, and adverse reactions, were evaluated to determine what information was most important to caregivers and how information needs change during the perinatal period. This was information generally available to caregivers provided by the following materials. The booklets issued by local government is called maternal booklets, which contains all detailed information recorded from pregnancy to childhood [23], and leaflets issued by pharmaceutical companies, with informative graphs. However, these sources were insufficient and not standardized.

The content of each session was established by combining parental needs with Health Belief Model concepts (used to explain the adoption of preventative health measures), such as increasing knowledge of VPD severity and susceptibility and vaccination benefits and decreasing barriers, e.g., anxiety. After identifying parental information needs, health professionals working in infant immunization were interviewed to determine the current educational situation and information needs during the pre- and postnatal period up to age 1 month. The educational content was then refined for each stage, and experts verified its validity.

The authors created three educational pamphlets reflecting the content of each intervention session. The pamphlets were designed for mothers and had understandable text and colored illustrations. The cover page contained key points regarding each intervention, which educators read to participants during the education sessions. The body of each pamphlet contained detailed information

Download English Version:

<https://daneshyari.com/en/article/5536565>

Download Persian Version:

<https://daneshyari.com/article/5536565>

[Daneshyari.com](https://daneshyari.com)