

# Necessary Content of Information Concerning the HPV Vaccine as Assessed by Mothers of Girls

Junko Shida\*, Yumiko Tsuchiya\*, Kyoko Inoue\*, Kunihiro Maeda\*  
and Michiyasu Yamaki\*\*

\*Department of Nursing, Yamagata Prefectural University of Health Sciences  
260 Kamiyanagi, Yamagata-shi, Yamagata 990-2212, Japan  
jshida@yachts.ac.jp

\*\* Department of Occupational Therapy, Yamagata Prefectural University of Health Sciences  
260 Kamiyanagi, Yamagata-shi, Yamagata 990-2212, Japan

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**Purpose:** This study aimed to clarify information considered necessary by mothers of girls approaching the recommended age for human papillomavirus (HPV) vaccination for making decisions whether or not to have their daughters vaccinated.

**Methods:** All research subjects were from one city and one town of Prefecture A in the Tohoku Region in Japan. Fourteen elementary schools provided consent to participate in the survey. Of the 684 parents/guardians of the 5th and 6th grade girls at these schools, 272 responded to the postal self-administered questionnaire survey. The data comprised the freely described content of the questionnaire. Berelson's content analysis method was used to analyze the "information considered necessary by mothers when making decisions concerning HPV vaccination."

**Results:** Of the 272 respondents, 129 provided freely written descriptions. Of these, the descriptions of 125 mothers (mean age,  $41.7 \pm 5.1$  years) were subjected to analysis. The content of the subjects' descriptions could be divided into 279 recording units. The number of recording units per respondent was 2.2. Ten categories were formed pertaining to information considered necessary by the mothers of girls not yet vaccinated against HPV when making decisions concerning HPV vaccination. These included, in order of the number of recording units from high to low, "Actual data demonstrating the degree and incidence of specific adverse events", "Preventive effect of the HPV vaccine on cervical cancer", "Basic knowledge of HPV and cervical cancer", "Safety of the vaccine over a prolonged period after vaccination" and "Vaccination site and schedule".

**Conclusions:** When making decisions concerning HPV vaccination, mothers sought information on basic knowledge about HPV and cervical cancer. They also sought information on the effects, adverse reactions, safety over a prolonged period after administration, and limitations of the vaccine.

**Keywords:** Human papillomavirus (HPV) vaccine, cervical cancer, information

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## I. Introduction

In Japan, the incidence of cervical cancer is rapidly increasing among women in their 20s and 30s. In particular, there has been a marked increase in the number of affected individuals between the ages of 20 and 29 years in recent years, with about a 4-fold increase over the past 30 years<sup>1)</sup>. While cervical cancer is a serious disease that could cause death if advanced, some characteristic features distinguish this cancer from others. First, precancerous lesions can be discovered in an examination<sup>2)</sup>. Second, in most cases, the cause can be attributed to persistent human papillomavirus (HPV) infection, and a

preventive vaccine has been developed for certain types of HPV associated with the pathogenesis of cervical cancer<sup>2-4)</sup>. The HPV vaccine was approved in the United States in 2006, and also in Japan in 2009. Since HPV is mainly transmitted by sexual act the preventive effects of the vaccine on cervical cancer can be optimized by administering it before the first sexual experience<sup>2)</sup>. Thus, the HPV vaccine is commonly administered to adolescent girls, and accordingly, the standard vaccination age in Japan is currently 13 years old<sup>5)</sup>.

In Japan, implementation of HPV vaccination has led to an increase in public interest regarding its safety and efficacy, mainly among parents of girls who are

targets of vaccination. While municipalities, which are responsible for administering HPV vaccines, play a major role in providing basic information about the vaccine, Matsuhisa et al. reported that only about half of parents/guardians who had their children vaccinated had an understanding of the vaccine's effects<sup>6</sup>). If parents/guardians lack an accurate understanding of the HPV vaccine, their influence on children who represent vaccination targets is also of concern. Children, as the ones receiving HPV vaccination, have the right to receive an explanation, and to be involved in their own decision-making. However, if parents/guardians have a misconception or insufficient understanding regarding the HPV vaccine, they would not be able to provide a full explanation to their children, depriving their children of the opportunity to exercise their basic right.

Furthermore, we think that explaining this to children is difficult in a way that is different from explaining other infectious disease vaccines administered during childhood. This is because HPV is sexually transmitted by sexual act<sup>2</sup>). It is in this respect that HPV infection, which is considered preventable by the vaccine, differs from influenza and measles, i.e., infectious diseases that are transmitted via airborne or droplet infection<sup>7</sup>). We suspected that some parents/guardians would be at a loss about what to convey and how, when explaining HPV infection to their children. In addition, it has not been long since HPV vaccination became available, and thus an insufficient amount of data has accumulated regarding its adverse events<sup>8</sup>). This is another aspect that distinguishes this vaccine from other vaccines, which likely increases parents/guardians uneasiness when they make decisions about the vaccination. In this context, we thought that the information sought by parents/guardians in considering HPV vaccination might differ from that concerning other childhood infectious disease vaccines.

In recent years, there has been an increasing number of reports on knowledge pertaining to the HPV vaccine and cervical cancer, as well as studies concerning HPV vaccination intention<sup>6) 9) 10)</sup>. On the other hand, hardly any reports exist regarding the content of information sought by parents/guardians before HPV vaccination, or explanations provided to children at the time of vaccination.

Therefore, we used a self-administered questionnaire to survey the level of awareness among parents/guardians regarding HPV vaccination and their

explanations to their children, as well as how decisions are made, with an ultimate objective of constructing a support system in which both parents/guardians and children can form decisions regarding HPV vaccination based on a complete and accurate understanding of the vaccine. The present study addressed a part of this objective, and aimed to determine the information considered necessary by mothers of girls approaching the recommended age for HPV vaccination for making decisions on whether or not to have their daughters vaccinated.

## II. Methods

### 1. Participants

Participants were 684 parents/guardians of 5th and 6th grade girls from 14 elementary schools, which provided consent to participate in the survey, in one mid-size city and one rural town of Prefecture A in the Tohoku Region in Japan. Of these, responses of 272 (39.8%) who completed a postal self-administered questionnaire survey were subjected to analysis.

### 2. Survey procedures

The 14 schools surveyed in this study were selected as follows: first, we explained the intent of the survey directly to the respective Board of Education in each city and town, and sent out documents describing the purpose and method of the survey to all 41 elementary schools in the areas requesting their participation. Of these, 14 schools agreed to cooperate, and the survey was conducted in all of these schools.

The questionnaire survey was conducted in December 2012. The explanation form regarding the study, the questionnaire, and a return envelope were distributed to parents/guardians through children from schools. The questionnaires were collected by mail addressed to the researchers, and participants who returned the completed questionnaire were considered to have provided consent to participate.

### 3. Survey content

The self-administered questionnaire used for the survey consisted of questions on characteristics (sex, age, relationship to the child) and those regarding the HPV vaccine. Specifically, the questionnaire asked respondents to answer the following question

freely (in writing): “When deciding whether or not to have your daughter receive HPV vaccination, what information would you consider necessary to make your decision?”. Within the free writing content, we noted quite a few responses concerning “preferred sources of information on the HPV vaccine” in addition to “information considered necessary by parents for making decisions concerning HPV vaccination”. As such, we analyzed the response data on preferred sources of information as well.

#### 4. Analysis

Data were analyzed according to the content analysis method as described by Berelson<sup>11)</sup>. Specifically, recording units were defined as phrases in the information source that describe “information considered necessary by mothers when making decisions concerning HPV vaccination”. Each context unit was defined as the entire descriptive content of an individual subject.

Next, regarding “information considered necessary by mothers when making decisions concerning HPV vaccination”, individual recording units were categorized by similarity of semantic content, and the categories were named to reflect accurately their descriptions. Coding and category names were examined and reviewed repeatedly among researchers. Finally, the frequency of appearance of each recording unit encompassed in each category was quantified and tallied by category.

Category reliability was calculated and evaluated by two researchers of nursing sciences with experience in qualitative research according to Scott’s equation<sup>12)</sup> to determine agreement rates for categories.

#### 5. Ethical considerations

The present study was approved by the ethics committee of Yamagata Prefectural University of Health Sciences. Participants received a written explanation that specified the research objective and clarified that their responses were voluntary, anonymous, and would be mailed back by respondents themselves. In addition, they were assured that no one else would receive information on their response status (i.e., a response or the lack thereof would not affect the parent, the child, or their relationship with the school). A written explanation

was also given specifying that the research findings would be presented at academic meetings or appropriate academic journals.

### III. Results

#### 1. Participant characteristics

Of the 272 parents/guardians who responded to the self-administered questionnaire survey (response rate, 39.8%), 129 answered the items which requested free writing. Data on respondent relationships with the child indicated that 125 (96.9%) were mothers, one (0.8%) was a father, one (0.8%) was a grandmother, and two (1.6%) did not specify. In the present survey, we selected 125 mothers (mean age  $\pm$  standard deviation, 41.7  $\pm$  5.1 years) as the subjects of analysis, considering that participant background could affect the results of the analysis.

#### 2. Information considered necessary by mothers for making decisions concerning HPV vaccination

The descriptive content of the responses was divided into 129 context units and 279 recording units. The number of recording units per individual was 2.2. After excluding written content that did not pertain to the topic, abstract writing, or writing content that was unclear in meaning, data pertaining to “Information considered necessary by mothers for making decisions concerning HPV vaccination” that were subject to analysis included 183 recording units. After coding these 183 recording units according to their similarity in written content, 10 categories were formed to represent the information considered necessary by mothers of girls approaching the recommended age for HPV vaccination when making decisions concerning HPV vaccination (**Table**).

Below is a discussion of each category, listed in descending order of the number of recording units. Categories are enclosed in “quotation marks,” and the number of recording units comprising each category, followed by the proportion (of the total recording units), are shown in the parentheses.

1. “Actual data demonstrating the degree and incidence of specific adverse events” (49 recording units, 26.8%): This category comprised recording units such as ‘The degree of adverse events’, ‘What kind of adverse events are possible?’, ‘Is there pain

at the time of vaccination?’ and ‘Data on adverse events’. Content from these units revealed that mothers sought actual data regarding the incidence and degree of specific adverse events that can occur when receiving the HPV vaccination.

2. “Preventive effect of the vaccine on cervical cancer” (42 recording units, 23.0%): this category comprised recording units such as ‘How well can the vaccine prevent cervical cancer?’ and ‘How effective is the vaccine?’. Content from these units demonstrated that mothers sought information on the preventive effect of HPV vaccination on cervical cancer.

3. “Basic knowledge of HPV and cervical cancer” (23 recording units, 12.6%): This category comprised recording units such as ‘What does HPV infection entail?’, ‘How does HPV infection occur?’ and ‘What kind of disease is cervical cancer?’. Content from these units revealed that parents sought information on the nature of HPV as a virus, infection routes, the nature of cervical cancer, and the symptoms caused by cervical cancer.

4. “Safety of the vaccine over a prolonged period after vaccination” (16 recording units, 8.7%): This category comprised recording units such as ‘How

well does the safety hold up?’ and ‘Does it have any effects on future pregnancy or childbirth?’. Content from these units revealed that mothers sought information on safety not only during HPV vaccination but also over a prolonged period during adulthood after vaccination.

5. “Vaccination site and schedule” (15 recording units, 8.2%): This category comprised recording units such as ‘Vaccination site’, ‘Number of vaccinations’ and ‘Information on the appropriate age for vaccination’. Content from these units indicated that mothers sought information on the number of shots required for HPV vaccination and the specific site of the body targeted for vaccination.

6. “Vaccination costs and subsidization policy” (14 recording units, 7.7 %): This category comprised recording units such as ‘Financial cost’ and ‘Vaccination cost subsidization’. Content from these units revealed that mothers sought information on the required costs of HPV vaccination, and estimated out-of-pocket expenses based on subsidization.

7. “Limitations of the vaccine in preventing cervical cancer” (10 recording units, 5.5%): This category consisted of recording units such as ‘Vaccination does not necessarily mean that cervical cancer will never

**Table** Information considered necessary by mothers for making decisions concerning HPV vaccination

Category name	Recording units
1. Actual data demonstrating the degree and incidence of specific adverse events	49 (26.8%)
2. Preventive effect of the vaccine on cervical cancer	42 (23.0%)
3. Basic knowledge of HPV and cervical cancer	23 (12.6%)
4. Safety of the vaccine over a prolonged period after vaccination	16 (8.7%)
5. Vaccination site and schedule	15 (8.2%)
6. Vaccination cost and subsidization policy	14 (7.7%)
7. Limitations of the vaccine in preventing cervical cancer	10 (5.5%)
8. The relationship between occurrence of cervical cancer and receiving or not receiving the vaccination	6 (3.3%)
9. The necessity of vaccination	5 (2.7%)
10. Vaccination rates within and outside Japan	3 (1.6%)
Total	183 (100%)

occur' and 'Periodic checkups are necessary even if one receives the vaccine'. Content from these units indicated that mothers also sought information on the limitations of the preventive effect on cervical cancer after vaccination.

8. "The relationship between occurrence of cervical cancer and receiving or not receiving the vaccination" (6 recording units, 3.3%): This category comprised recording units of 'Of those currently affected by cervical cancer, what proportion had received the HPV vaccine?', 'The likelihood of subsequently developing cervical cancer if one does not receive vaccination' and 'Comparison data regarding occurrence in those who did or did not receive the HPV vaccine'. Content from these units revealed that mothers sought data demonstrating a relationship between the HPV vaccination and occurrence of cervical cancer.

9. "The necessity of vaccination" (5 recording units, 2.7%): This category comprised recording units such as 'Why is the HPV vaccination necessary?', 'Is the vaccination necessary enough to warrant the painful experience?' and 'Why is it insufficient to simply go in for annual check-ups?'. Content from these units revealed that parents heard reports of various problems, such as adverse events, and sought information on the necessity of the HPV vaccination.

10. "Vaccination rates within and outside Japan" (3 recording units, 1.6%): This category comprised recording units of 'How many people receive the HPV vaccine within this prefecture and nationally?', 'Approximately how many people are vaccinated?' and 'Vaccination rates in other major nations'. Content from these units indicated that parents sought information on HPV vaccination rates not only within their prefecture and country, but in other countries as well.

### 3. Category reliability

We asked two researchers in nursing sciences to calculate agreement rates for our coding of the various categories using Scott's equation<sup>12)</sup>. As a result, "Information considered necessary by parents for making decisions concerning HPV vaccination" had reliability rates of 96.7% and 92.4% by the two researchers, while "Preferred sources of information

on the HPV vaccine and related matters" was found to have 100% reliability by both researchers.

## IV. Discussion

### 1. Participant status

In this study, 47.4% of the participants who cooperated with the questionnaire survey answered the items which requested free writing, with a mean of 2.2 recording units per respondent for the 125 mothers included in the analysis. Although the recovery rate was not very high (39.8%), the proportion of those who provided the written content was high, suggesting that the participants represented a population with high interest in cervical cancer and the HPV vaccine.

### 2. Category reliability

Category agreement rates of 70% or higher, as calculated according to Scott's equation, have been reported to be reliable<sup>12) 13)</sup>. In the present study, agreement rates were higher than 70% in all cases, supporting the reliability of the various categories.

### 3. Information considered necessary by mothers of girls approaching the recommended age for HPV vaccination for making decisions concerning HPV vaccination

The present study identified 10 categories representing the information considered necessary by mothers of girls approaching the recommended age for HPV vaccination when making decisions regarding whether to have their daughters vaccinated. The content of these categories included information pertaining to adverse reactions ("Actual data demonstrating the degree and incidence of specific adverse events"), effects ("Preventive effect of the vaccine on cervical cancer"), diseases ("Basic knowledge of HPV and cervical cancer"), vaccination schedules ("Vaccination site and schedule") and costs ("Vaccination costs and subsidization policy"). At the municipality that implemented the survey, the effects and adverse reactions of the vaccine, cervical cancer, vaccination sites and schedules, and fees are explained in writing or on the home page<sup>14)</sup>. In addition, taking varicella as an example of a vaccine administered during childhood, explanations are

provided on an overview of the disease and vaccine as well as all of the aforementioned content<sup>15</sup>). Because this explanatory content is published by the municipality, it is difficult to compare rigorously with that of the present study, which surveyed information that mothers regarded as necessary. However, our results indicate that much of the information considered necessary by mothers in making decisions concerning HPV vaccination agrees with the content explained when undergoing other preventive vaccinations administered during childhood or HPV vaccination.

On the other hand, the content in our study also included categories and recording units that could be considered characteristic of HPV vaccine. First is the category of “Limitations of the vaccine in preventing cervical cancer”. This is presumably because the preventive effect of the HPV vaccine on cervical cancer is thought to be limited. Common preventive vaccines administered to children for infectious diseases, such as measles and rubella, supposedly achieve more than 95% immunity with just one shot<sup>7</sup>). However, the effectiveness of the HPV vaccine to prevent cervical cancer is about 75% after three shots<sup>2) 16</sup>), and only in combination with medical check-ups would a 95% disease prevention rate be achieved<sup>2</sup>). Given this difference in effectiveness between the HPV vaccine and other infectious disease vaccines administered during childhood, it will be necessary that information concerning the limitations of the effect be transmitted accurately. We note that at the municipality that implemented the survey, the needs of mothers are likely being met because the limitations of the HPV vaccine in preventing cervical cancer are clearly stated on the home page as well<sup>14</sup>).

This study was characteristic in that it revealed mothers’ need to obtain information regarding the safety not only after vaccination but over a long period of time, as represented by the category, “Safety of the vaccine over a prolonged period after vaccination”. This is presumably due to the underlying problem that data based on long-term monitoring are still lacking<sup>8</sup>), given that the HPV vaccine is a new vaccine and hence only seven years have elapsed even in countries where vaccinations began ahead of Japan.

In this regard, this survey revealed that mothers also sought information on “The relationship between occurrence of cervical cancer and receiving or not receiving the vaccination”, which cannot be provided

by currently obtained data. The HPV vaccine is commonly administered in the early to middle teens overseas as well. Considering that cervical cancer is a disease that commonly affects people in their 20s and 30s, confirming the preventive effect of the vaccine will require follow up across a prolonged period of several years to several decades. Hence, it will be more than 10 years before actual data that show “The relationship between occurrence of cervical cancer and receiving or not receiving the vaccination” sought by mothers can be provided. However, our results suggest the need to come to terms with the fact that mothers are also seeking references on ‘The approximate proportion of people that developed cervical cancer among those who had been vaccinated’ when making decisions concerning vaccination. In addition, the fact that mothers showed interest in “Vaccination rates within and outside Japan” suggests that they were seeking information indicating conditions in other regions because the HPV vaccine was introduced only recently. Currently, information on “Safety over a prolonged period after vaccination” and “Vaccination rates within and outside Japan” is not transmitted by the municipality that implemented the survey. Therefore, we think that the information content to be transmitted needs to be considered in light of the information considered necessary by mothers. Additionally, responding to the mothers’ need to find objective information based on actual data will likely require that information be transmitted appropriately, focusing on information within Japan as well as other countries where HPV vaccinations began ahead of Japan.

Concerning the vaccination schedule in “Vaccination site and schedule”, the same content is also explained when undergoing other childhood infectious disease vaccinations<sup>15</sup>). This suggests that many mothers required information on the vaccination schedule at the time of HPV vaccine administration as well. The HPV vaccine, however, requires three shots over the course of six months<sup>5</sup>) when girls are at the age of 13 years, i.e., during the first year of junior high school in Japan, in order to acquire sufficient immunity. This is one aspect that makes the HPV vaccine different from other preventive infectious disease vaccines. Many mothers sought information regarding vaccination schedule, possibly because they were conscious about the need to adjust their schedules in order to have their daughters undergo vaccination in a planned manner, since children tend

to get busy with classes and extracurricular activities during the first year of junior high school.

The present study also identified the following categories, which are not necessarily characteristic of the HPV vaccine, but are likely attributable to the fluid situation surrounding HPV vaccination.

The first category is “Actual data demonstrating the degree and incidence of specific adverse events”. Fiscal year 2012, when the study was implemented, was a period during which HPV vaccinations, albeit voluntary, were actively carried out at the federal and municipality levels with public funding. Even then, mothers expressed great interest in “Actual data demonstrating the degree and incidence of specific adverse events”. As of September 2014, HPV vaccination was not actively recommended in Japan on the basis of reports of adverse events including chronic pain following vaccination<sup>17)</sup>. Thus, it was likely that mothers’ interest in adverse events has further increased from the time that this study was implemented.

The next category is “Vaccination costs and subsidization policy”. The HPV vaccine is quite expensive, costing about 50,000 yen out-of-pocket for three shots. In 2012, when this survey was conducted, the central and local governments were bearing vaccination costs, and those at the age specified by the municipality were able to receive HPV vaccination for free; there was, however, uncertainty regarding whether this public expenditure system would be continued. The high cost of the HPV vaccine, as well as the fluidity of the policy, could have increased mothers’ interest in “Vaccination costs and subsidization policy”. Today, HPV vaccination is provided free of charge to girls at the target age uniformly throughout the nation, since the vaccine has subsequently been included in the routine vaccination program in accordance with the Preventive Vaccination Law<sup>5)</sup>. At the municipality where the study was implemented as well, the home page clearly states that HPV vaccinations can be performed without any out-of-pocket costs<sup>14)</sup>.

#### 4. Study limitations

The present study targeted parents/guardians of 5th and 6th grade girls attending elementary schools that cooperated with the survey, and who answered the items that requested free writing; the final recovery rate was 39.8%. Based on these conditions, the

possibility that the subject population was limited and biased cannot be denied, and thus results from our participants might not fully reflect the realities of the parent population. Furthermore, due to time constraints, we did not make efforts to improve the recovery rate, such as sending out re-requests. In this regard, it would be necessary to take various active measures to increase the recovery rate and minimize selection bias. Future studies will be necessary to verify the results obtained in this study, such as by re-conducting the survey or extending the survey area, and to conduct a survey targeting fathers as well.

The survey was conducted in 2012, before the HPV vaccine was included for routine immunization. The situation in Japan surrounding HPV vaccination is changing, and currently (as of the end of June 2014), the Ministry of Health, Labour and Welfare does not proactively recommend HPV vaccination<sup>17)</sup>. Given that reports on adverse events are currently more prevalent than those on the effects of the HPV vaccine, it is likely that conducting the same survey would yield different categories with different numbers of recording units and distributions.

## V. Conclusions

The present study revealed that mothers of girls not yet vaccinated against HPV, when making decisions concerning HPV vaccination, were in need of information on “Actual data demonstrating the degree and incidence of specific adverse events”, “Preventive effect of the vaccine on cervical cancer”, “Basic knowledge of HPV and cervical cancer”, “Safety of the vaccine over a prolonged period after vaccination”, “Vaccination site and schedule”, “Vaccination costs and subsidization policy”, “Limitations of the HPV vaccine in preventing cervical cancer”, “Rates of cervical cancer with and without HPV vaccination”, “The necessity of vaccination” and “Vaccination rates within and outside Japan”.

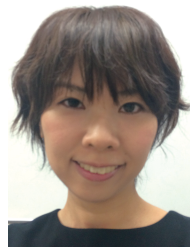
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**Name:**

Junko Shida

**Affiliation:**

Department of Nursing, Yamagata Prefectural University of Health Sciences

**Address:**

260 Kamiyanagi, Yamagata-shi, Yamagata 990-2212, Japan

**Brief Biographical History:**

2008- Assistant Professor, Yamagata Prefectural University of Health Sciences

**Main Works:**

- Shida J, Sugawara K, Goto J and Sekito Y. Relationship between self-esteem and living conditions among stroke survivors at home. *Japan Journal of Nursing Science*. 2013 ; Article first published online: 16 JUL,2013 DOI:10.1111/jjns.12024.

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