

HPV vaccination acceptability in young boys

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Abstract

Purpose. The aim of this study was to evaluate the comprehension and acceptance of HPV vaccination in parents of adolescent boys aged 11 to 15 years.

Methods. A cross-sectional survey was conducted by means of questionnaires sent directly to the homes of all families with young males aged between 11 and 15, residents of three municipalities of the Province of Brescia, Italy. The documentation also contained an informative leaflet summarizing the HPV-related disease characteristics, the burden of disease and the available strategies for prevention and treatment, illustrating the rationale of vaccination and describing the project and its phases. The questionnaire included questions on demographic data, acceptance and motivations for HPV vaccination. The collected data was analyzed using descriptive statistics. At the end of the study, parents who received the questionnaires were also offered the possibility of vaccinating their male sons for free.

Results. From a total of 1072 questionnaires sent, 161 were returned from the three selected municipalities (average response rate 15%); 97% of adolescent males involved in the study were Italian and 91% Catholic; 97% of parents declared themselves to be willing to vaccinate their sons: the principal motivation given (92%) was prevention of the disease, cancerous or not, related to viral infection. Among the respondents not willing to vaccinate their sons, the motivation was lack of information about the vaccine and the disease. At the end of the study, around 71 boys were vaccinated.

Discussion. To our knowledge, this is the first survey in Italy exclusively conducted on parents of adolescent males about the acceptability and feasibility of vaccination against HPV: a very high percentage of respondents was favorable to accept the vaccination for their sons, the main motivation being the fact that parents considered protecting their sons from HPV-related diseases highly important. Of the 161 boys targeted by the questionnaire, 71 decided to receive the 3 doses of HPV vaccination (44%). Data suggests that HPV vaccination is acceptable to families for their male sons and that information is important in the decision-making process.

Key words

- HPV vaccine
- young male
- cervical cancer
- vaccine acceptability
- public health system
- HPV vaccination
- STI

INTRODUCTION

Human Papilloma Virus (HPV) is the cause of the most common sexually transmitted infection in the world. Males, as well as females, have an important role in the transmission of HPV. HPV DNA can be detected in the cervical tissue in up to 45% of women 20-24 years of age [1-5]. In men, the prevalence ranges from 20 to 65% and is high at all ages [6, 7-10] and are related to oral cancers in around 25-35% of cases, anal cancer in 90% of cases, and penile cancer in 40% of cases [9]. In a recent publication it has been estimated that in Europe more than 340 000 cases/year of HPV vaccine-preventable diseases affect only women. A similar number is also evidenced in men (including more than 320 000 cases of genital warts, 12 000 cases of head and neck cancer, more

than 1600 cases of anal cancer and around 1000 cases of the penile cancer [8, 9, 11, 12].

In the USA in October 2011, following the approval of the quadrivalent vaccine use also on males, the American Centers for Diseases Prevention and Control (CDC) recommended that young boys as well as girls should get immunised against HPV [13]. The same was recommended in Canada by the National Advisory Committee on Immunization (NACI) [14] and in Australia [15] by the Pharmaceutical Benefits Advisory Committee (PBAC), even if Australia had high vaccine coverage in females and herd immunity was expected and demonstrated. Surveys conducted with different methodologies on the general male population at risk or over 18 years have shown varying degrees of knowledge and acceptability of HPV vaccination [16-25]. In Italy,

in a survey conducted among high school students and their parents, both mothers and fathers (68% and 65% respectively) were willing to vaccinate their children.

In order to propose new vaccination strategies and ensure high acceptability and coverage, research is essential in terms of population needs and acceptability in order to better understand and implement vaccination strategies accordingly. Current research about the attitudes and acceptance of an HPV vaccine has largely focused on females [26-28]. As regards females, studies also correlate awareness with acceptability and demonstrate that awareness campaigns of any kind consistently raised acceptability to vaccinate [29]. Considerably less is known about acceptance of HPV vaccine for males although every day new data is being produced worldwide. A recent study review of available published literature on acceptability among parents, health care providers and young males concluded that acceptability median was around 74%. It also stressed the small number of studies available on males and the urgent need for new studies that incorporate more recent data on HPV-related diseases and recent vaccine efficacy in order to correctly evaluate acceptability [30]. Another study found that acceptability improved when parents received information about the diseases, advantages and importance of vaccination [31]. When information was given to males between 18-26 years of age, results showed that irrespective of the HPV message (whether it was centred on genital warts, female HPV diseases or head and neck HPV cancers) intent to be vaccinated increased [32]. In the USA parents seem to want to vaccinate their male sons. Recently a study showed that from a sample of parents, 62% answered the questionnaires about intention to vaccinate, from which 90% declared they wanted to vaccinate their sons [33]. Recently in England there has been a change in the use of HPV vaccine; now they use the quadrivalent vaccine, which is approved for use in males and females, primarily to offer also protection against genital warts. This has raised several questions about male vaccination possibility in England and from a recent survey conducted among boys between 16-18 years old attending school, showed that HPV vaccine is also accepted among this population and that information about disease implications is vital to increase acceptance [34].

In Italy data about HPV vaccination acceptability in females is scarce and little is known about males. One study, centred on females aged 18 to 26 years to evaluate acceptability feasibility in Italy, showed that where vaccination was offered for free to this age range at least 56% of the population interviewed received one vaccine shot when offered actively by the local health system [35]. Previous Italian research data about vaccination offer to both genders conducted by school based questionnaire about HPV knowledge and vaccine acceptability concluded that Italian students and parents tend to underestimate the likelihood of HPV infection and the importance of the burden of HPV-related diseases [36]. The purpose of this study was to evaluate the understanding and acceptance of HPV vaccination on parents of adolescent boys aged 11 to 15 years by means of questionnaires sent directly to their homes.

METHODS

The Ethics Committee of the Hospital of Brescia approved the survey on January 11, 2011 as a no-profit, no-sponsored study.

A questionnaire was prepared by the authors of the study, and was printed by INFORMA-CRO srl. A copy of this questionnaire, both in Italian and in English, can be sent on request contacting the corresponding author at: dott.tisi@gmail.com.

From March 2011 to September 2011 information leaflets on HPV burden of disease and questionnaires to evaluate vaccine acceptability were sent to all families with young males aged between 11 and 15, residents of three municipalities of the Province of Brescia, Italy (Montichiari, Orzinuovi and Roncadelle).

The list of families with male adolescents was obtained from the registry lists of Brescia residents, provided by the previously selected municipalities. Families were also made aware that their local pediatricians and general practitioners were informed that the survey was taking place. A free phone line was also activated, operated by trained physicians coordinated by the department of gynecology and obstetrics, in case further information on HPV-related diseases was required by the families receiving the questionnaire. Taking into consideration that some families already had a basic acquired knowledge of HPV diseases and of the vaccination offered to girls by the National Health System yet none or little on the possibility of also vaccinating males, the educational content was centered on males and their burden of disease. The information leaflet was divided into different sections summarizing the disease characteristics, the burden of disease and the available strategies for prevention and treatment, illustrating the rationale of vaccination, the project and its phases and listing in detail what was being asked to the families about the project. All of this was supported by detailed information and didactic diagrams.

The questionnaire contained questions on demographics data (place of birth, municipality of residence, education, profession and age of the parents), willingness to accept or not the proposed vaccination and provided several options for returning the finished questionnaire: either to the hospital help desk, by fax, through a dedicated internet based website or by phone calling the toll-free number, which was also activated to offer answers to all doubts about the disease or the project. Each questionnaire was anonymous, although a unique numeric code was necessary in order to identify the study's population cohort that answered the questionnaire. The collected data was analyzed using descriptive statistics (mean, standard deviation for continuous variables and absolute and percentage distributions for discrete variables).

In January 2011, the quadrivalent anti HPV vaccine summary product characteristic (SPC) already included vaccine immunogenicity data on children and adolescents irrespective of the sex ("Il vaccino produce inoltre la formazione di anticorpi in bambini ed adolescenti di età compresa tra 9 e 15 anni") this evidence of immunogenicity also in males younger than 14 years of age permitted that parents who received the questionnaires

were also offered the possibility of vaccinating their male sons for free with the quadrivalent HPV vaccine (types 6, 11, 16, 18). In June 23 2011, "Gardasil" was authorized for males up to 26 years of age and in September 2011, following the survey, we started to vaccinate all responders willing to receive the vaccine.

RESULTS

A total of 161 completed questionnaires were returned, from a total of 1072 questionnaires sent. The average response rate, regardless of municipality of residence, was 15%: 15.5% specific to the Montichiari municipality (87/562), 12.7% for Orzinuovi municipality (41/322) and 17.5% for Roncadelle municipality (33/188).

Table 1 shows the distribution of parents in relation to selected socio-demographic characteristics. The questionnaire was completed mainly by mothers, around 85%. The fathers resulted to be in general older than the mothers, respectively, 54% of fathers and 32% of mothers reported an age ≥ 45 years. 57% of the mothers and 52% of the fathers had a high school diploma and the majority of the mothers declared themselves to be housewives (38%) while the majority of fathers (33%) were workers.

Table 2 shows the characteristics of the adolescent males between 11 and 15 years of age involved in the

study: 96% were Italian and 91% Catholic. The average age was 13 years of age, 67% attended middle school. The majority, 60%, had only one other sibling, 22% were an only child, the remaining 20% had more than one brother or sister. From the whole population, 43% declared themselves to have at least one sister already vaccinated against HPV.

A big proportion of parents, 97%, declared themselves to be willing to vaccinate their sons if the vaccine was proposed or available to them for free: the principal given motivation was prevention of any disease, this included pre-cancerous lesions, cancer or benign lesions such as genital warts, related to HPV infection (92%), followed by feeling that it was right to offer the vaccine equally to both genders (5%). Only 6 families, (3%) rejected the proposed vaccine giving as motivation that there is not enough information available about the vaccine. In 80% of cases the only available information they had the chance to come upon, in order to understand HPV infection and impact, was the informational leaflet attached to the questionnaire itself.

At the end of the study (October 31, 2011), all subjects that actively contacted our call center were vaccinated. We were not allowed to directly invite any subject because the questionnaires returned were anonymous. Around 71 boys were vaccinated (44% of all answered questionnaires).

Table 1

Distribution of parents by gender, age and some socio-demographic characteristics

	Mother		Father	
	N	%	N	%
Age (years)				
< 40	35	21.7	9	5.6
40-44	59	36.7	50	31.1
45-49	40	24.8	56	34.8
≥ 50	12	7.5	31	19.2
Missing	15	9.3	15	9.3
Mean age	42.9 \pm 4.9		45.9 \pm 5.1	
Education				
Elementary	2	1.2	4	2.5
Middle school	68	37.9	71	44.1
Higher school	77	12.4	68	42.2
University	14	24.8	16	9.9
Missing	-	-	2	1.3
Occupation				
Unemployed	2	1.2	3	1.9
Housewife	61	37.9	-	-
Worker	20	12.4	53	32.9
Employee	40	24.8	30	18.6
Manager	3	1.9	5	3.1
Self employed	-	-	29	18.0
Other	29	18.0	34	21.1
Missing	6	3.7	7	4.4
Who answered the questionnaire	129	80.1	32	19.9

All received 3 dose vaccination schedules. Doses of the vaccine were provided by the Regional Public Health Office of Lombardy who also authorized this vaccination program on May 23, 2011.

DISCUSSION

Extending vaccination to boys will not only protect males but it will also reduce rates of HPV related cases among females (via herd immunity). In some countries, local health authorities have already taken into consideration the previous unknown HPV burden in males and have started to offer vaccination campaigns also for males. The United States of America, Australia and Canada are among the first countries to recommend and offer routine vaccination in boys too [13-15].

This is the first survey in Italy exclusively conducted on parents of adolescent males about the acceptability and feasibility of vaccination against HPV infection: it was possible to propose an active offer of vaccination, even if only through a written communication, involving families of the three municipalities. A total response rate of 15%, for a questionnaire that was sent by traditional mail can be considered a good rate [22], also considering that no other active intervention was programmed to remind families to complete the questionnaire, such as telephone calls or an eventual reminder letter, nor any type of information about the possibility of vaccination offer of males; in this sense studies have observed that additional actions exponentially increase the answer rates of a survey [37]. According to the observational target of the study, returned questionnaires were anonymous, so a second call was not performed to non responders.

The study was designed by University of Brescia according to Spedali Civili of Brescia Ethic Committee. The source of information from public health Institutions probably determined a very high (97%) proportion of respondents willing to vaccinate their male sons. The main motivation being the fact that they considered the disease of high importance also for males having the right to receive the vaccine. It should be noted that, at present, the medical community and public opinion in Italy consider HPV vaccination to be a vaccine needed and indicated exclusively to females. The results also showed that among respondents not willing to vaccinate their sons, the motivation was lack of information about the vaccine and the disease. We have also to affirm that the high proportion of parents in favour of vaccination may be a bias due to the high percentage of ones having a daughter already vaccinated: probably only already sensibilized people participated the survey. On these bases, we suppose that a more invasive campaign, than a simple informative leaflet on the disease risks, might obtain a better response rate.

The results obtained emphasize some aspects, which are at the base of the external limits found in order to implement a working vaccination offer. Due to the fact that the information campaign was necessarily and deliberately non-invasive (no further actions were taken to increase response rates), it was not possible to collect socio-demographic information on the non respondents. Also, the fact that the results relate to a small,

selected area of Italy makes it difficult to extend the results to the entire country. Moreover, the high rate of acceptance of vaccination among respondents creates a bias: usually families that find the time to answer the questionnaire have already a predisposition to the importance of the vaccine, showing interest about the disease predisposes them to answer positively to a possible offer. In the future greater efforts are needed to inform the population about the disease burden and importance of vaccination campaigns. Overall acceptability in males seems to be quite high in this particular area of Italy.

Following the survey, we also measured feasibility by offering the vaccine free of charge to the families that declared to be willing to vaccinate their male sons. Out of 161 boys potentially eligible for the HPV vaccination and targeted through the questionnaire, 71 have de-

Table 2
Distribution of adolescents by age and some socio-demographic characteristics

	Adolescents	
	N	%
Age (years)		
< 12	21	13.0
12-13	77	47.8
14-15	63	39.2
Missing		
Age median \pm ds	13.1 \pm 1.3	
Level of study		
School	108	67.1
High School	50	31.3
Missing	3	1.8
Number of brothers or sisters		
0	36	22.4
1	97	60.2
2	20	12.4
\geq 3	3	5.0
Missing	3	1.9
Mean number of brothers/sisters \pm ds	1.1 \pm 1.1	
N of vaccinated brothers/sisters		
0	55	34.2
1	69	42.9
3	1	0.6
Missing	36	22.3
Nationality		
Italian	147	95.7
Other	6	4.3
Religion		
Catholic	147	91.3
Islamic	6	3.7
Other	2	1.3
Missing	6	3.7

cided to receive the 3 doses of HPV vaccination (44%).

The relatively low percentage of vaccinated subjects, which also declared themselves in favour of vaccination, could be explained as follows:

- 1) a direct call was not performed: all the questionnaires returned were anonymous so we were not able to directly call the subjects. We offered the vaccinations to all the subjects that actively have called our Center (the procedure was clearly explained in the information given with the questionnaires);
- 2) the vaccination offer were performed when the collection of all questionnaires was concluded, so we started the vaccinations about 4-6 months after the subjects had responded. Without the possibility to remember them about this offer, it was easy to forget it after 4-6 months. In reality, a large number of subjects called our Center after the closure of the Study asking to be vaccinated, unluckily they self declared to have not received the letter and that they found out from classmates that were vaccinated, so we were not able to offer them the vaccination for free.

We suppose that a better percentage of response could have been improved by an active invitation with a direct call to subjects' parents.

Throughout the vaccinated population, no adverse effects were reported and all of them completed the 3 dose schedule. This proves acceptability from parents and sons who demonstrated high interest in getting vaccinated after an invitation letter and in turn makes us think that an active and free offer also to males, which would make HPV vaccination a non-gender based vaccination, could be quite feasible taking into considera-

tion the good response obtained. Most likely, having a universal vaccination would also boost female coverage. Request for vaccination did not only come from the informed families, but after the study ended, several requests from other families of the three municipalities were received to vaccinate their sons. The good feedback of all participating subjects and the absence of any adverse or unexpected event could have increased the interest of parents of classmates and friends of vaccinated young males. This change of mind in parents that did not respond to our initial vaccination purpose suggests that an active call program could obtain good acceptance.

Given the importance shown by the informative material sent to the families about the disease epidemiology and importance of vaccination, it seems necessary to start promoting educational interventions on the population more actively, in order to increase and improve knowledge about the disease and the benefits that a universal anti-HPV vaccination can produce.

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Conflict of interest statement

The authors declare that no competing interests exist.

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